US009421045B2

(12) **United States Patent**
Justin

(10) **Patent No.: US 9,421,045 B2**
(45) **Date of Patent: Aug. 23, 2016**

(54) **BONE STABILIZATION DEVICE AND METHOD**

(71) Applicant: **FlexFix LLC**, Logan, UT (US)
(72) Inventor: **Daniel F Justin**, Orlando, FL (US)
(73) Assignee: **FlexFix, LLC**, Logan, UT (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 201 days.

(21) Appl. No.: **14/220,132**
(22) Filed: **Mar. 20, 2014**
(65) **Prior Publication Data**

US 2014/0207138 A1 Jul. 24, 2014
US 2016/0128742 A9 May 12, 2016

Related U.S. Application Data

(63) Continuation of application No. 13/423,914, filed on Mar. 19, 2012, now Pat. No. 8,834,468, which is a continuation of application No. 12/027,521, filed on Feb. 7, 2008, now Pat. No. 8,167,881, which is a continuation-in-part of application No. 11/777,846, filed on Jul. 13, 2007, now abandoned, and a continuation-in-part of application No. 11/777,872, filed on Jul. 13, 2007, now abandoned, and a continuation-in-part of application No. 11/777,892, filed on Jul. 13, 2007, now Pat. No. 8,128,626.

(60) Provisional application No. 60/913,696, filed on Apr. 24, 2007.

(51) **Int. Cl.**

A61B 17/72	(2006.01)
A61B 17/70	(2006.01)
A61B 17/80	(2006.01)

(Continued)

(52) **U.S. Cl.**
CPC ***A61B 17/72*** (2013.01); ***A61B 17/7044*** (2013.01); ***A61B 17/7059*** (2013.01); ***A61B 17/7071*** (2013.01); ***A61B 17/7208*** (2013.01); ***A61B 17/7233*** (2013.01); ***A61B 17/7275*** (2013.01); ***A61B 17/80*** (2013.01); ***A61B 17/864*** (2013.01); ***A61B 17/866*** (2013.01); ***A61F 2/91*** (2013.01); ***A61M 29/02*** (2013.01); *A61B 17/7064* (2013.01); *A61B 2017/00004* (2013.01); *A61F 2/0077* (2013.01); *A61F 2/82* (2013.01); *A61F 2220/0075* (2013.01); *A61L 2400/16* (2013.01); *A61L 2430/02* (2013.01)

(58) **Field of Classification Search**
USPC 606/62–68, 108, 194, 198; 623/1.11, 623/1.15
See application file for complete search history.

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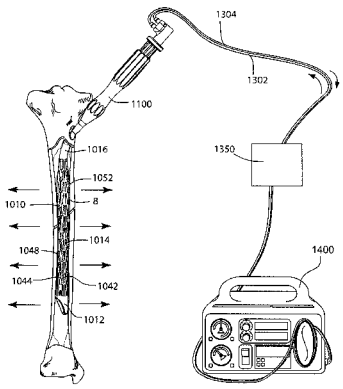
Primary Examiner — Jan Christopher Merene
Assistant Examiner — Steven Cotroneo

(57) **ABSTRACT**

There is disclosed a device and method for stabilizing a bone. The device includes a polymer with a glass transition temperature. The polymer is relatively deformable at a temperature above the glass transition temperature and relatively rigid at a temperature below the glass transition temperature. The device, while the polymer is above the glass transition temperature, is responsive to a bending force to bend during insertion into the intramedullary canal of the bone. The device, while the polymer is below the glass transition temperature, is relatively rigid and able to provide reinforcement to the bone.

6 Claims, 43 Drawing Sheets



(51) **Int. Cl.**

A61B 17/86	(2006.01)
A61F 2/91	(2013.01)
A61M 29/02	(2006.01)
A61B 17/00	(2006.01)
A61F 2/00	(2006.01)
A61F 2/82	(2013.01)

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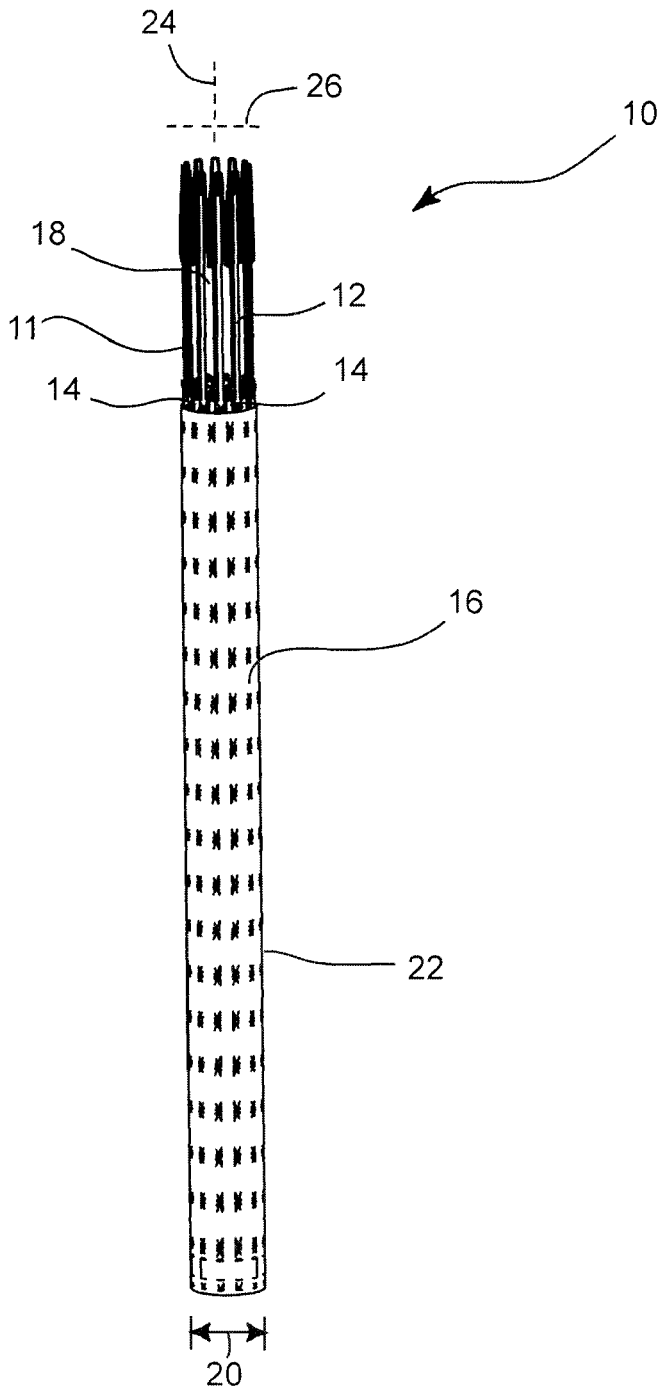

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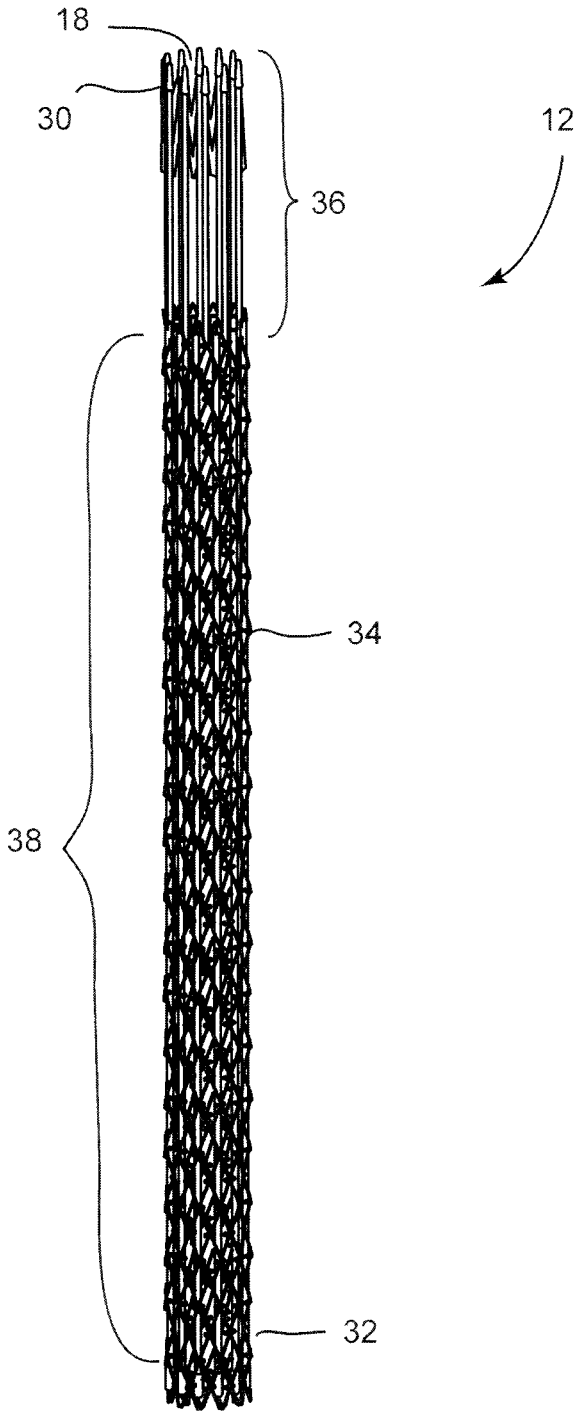


Fig. 2

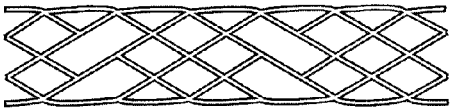


Fig. 3A

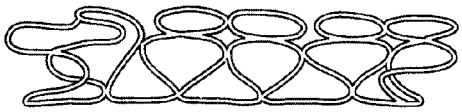


Fig. 3B

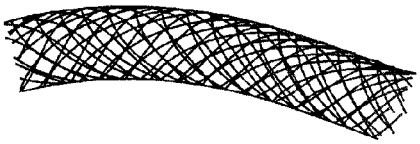


Fig. 3C

Fig. 3D

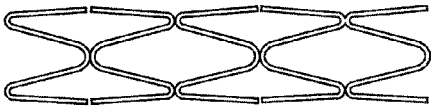
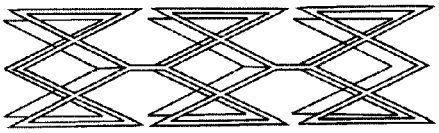


Fig. 3E



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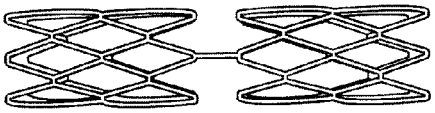


Fig. 3G

Fig. 3H

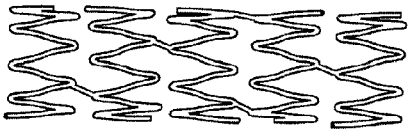
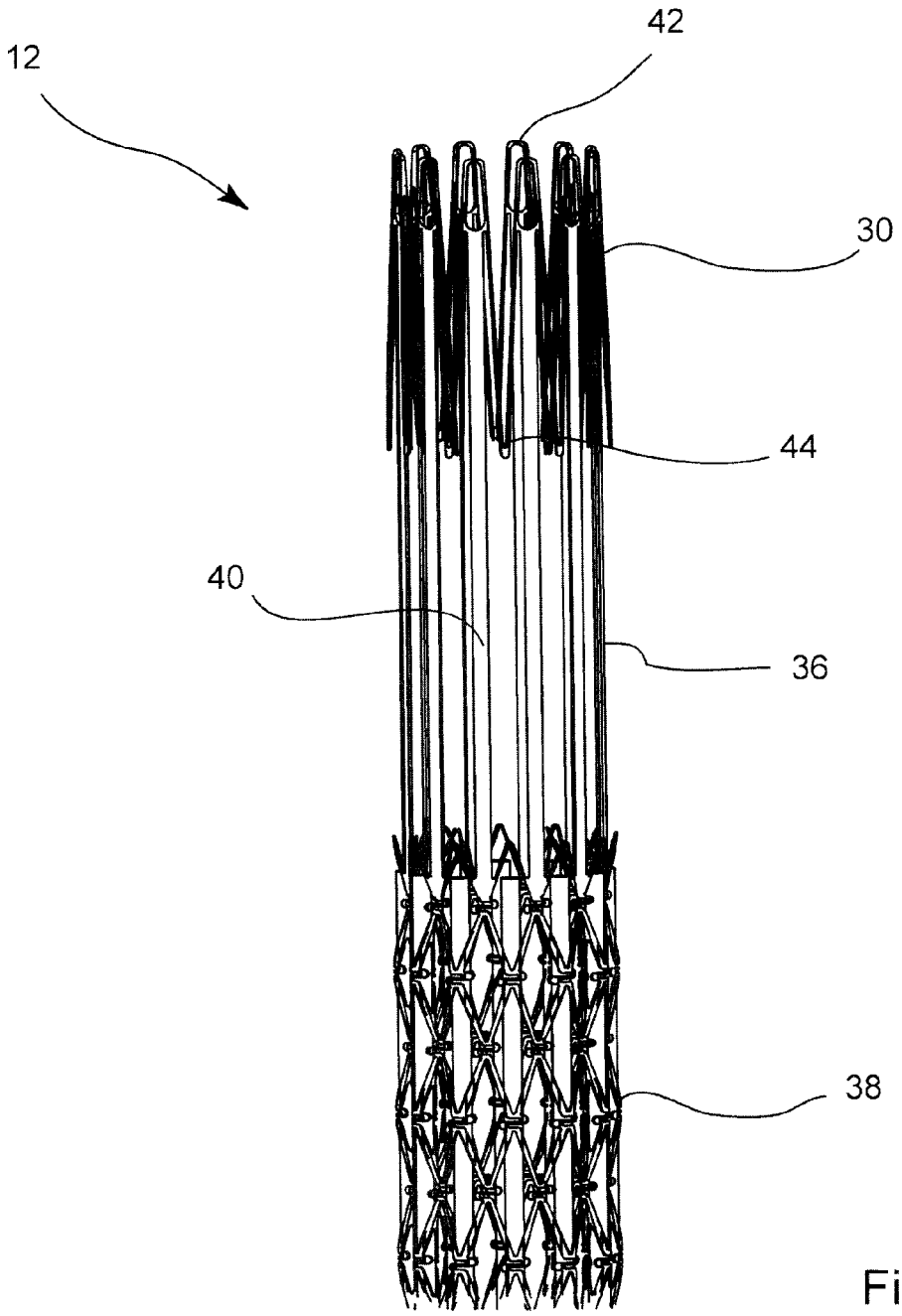


Fig. 3I



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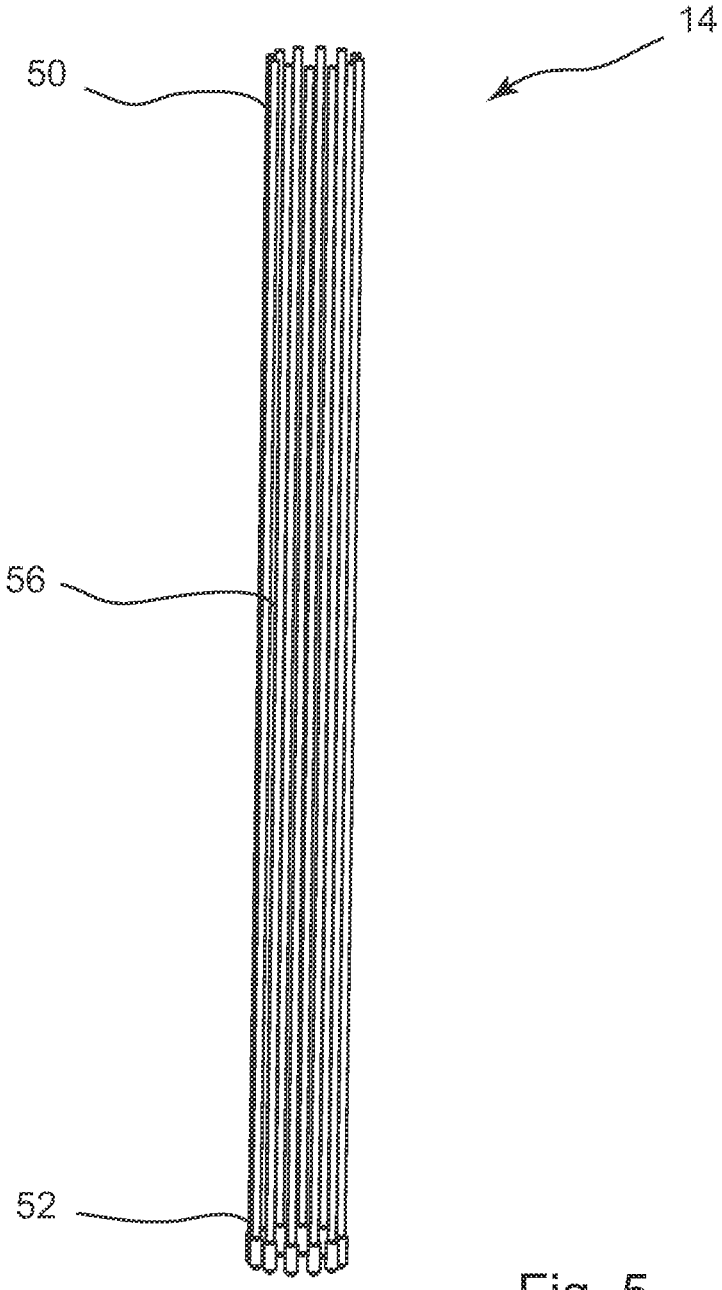
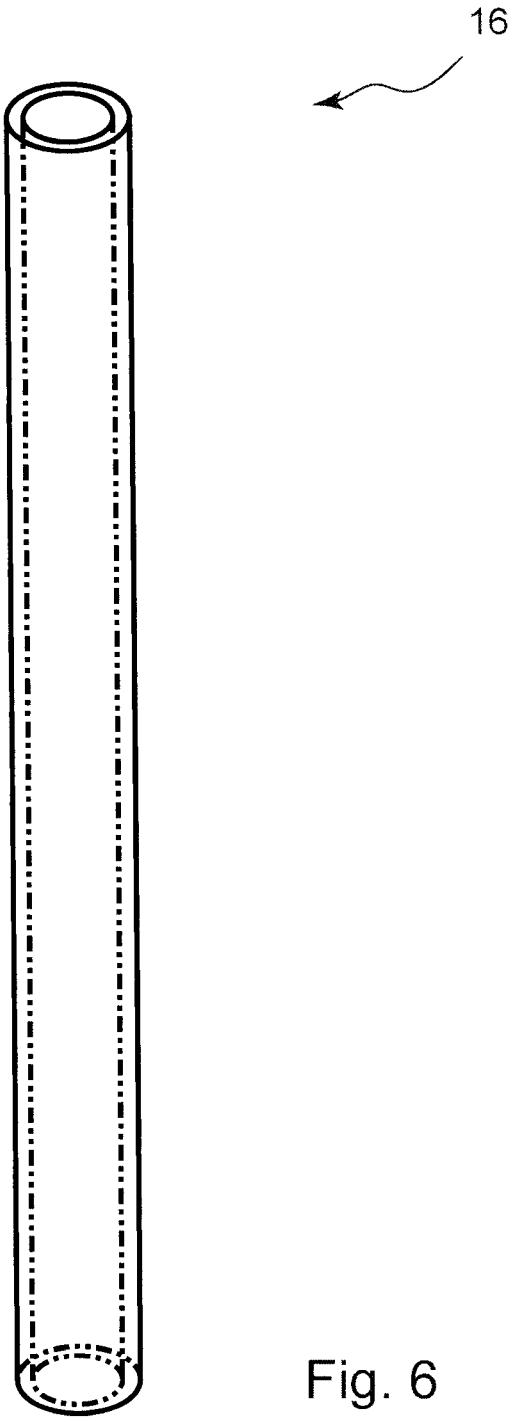


Fig. 5



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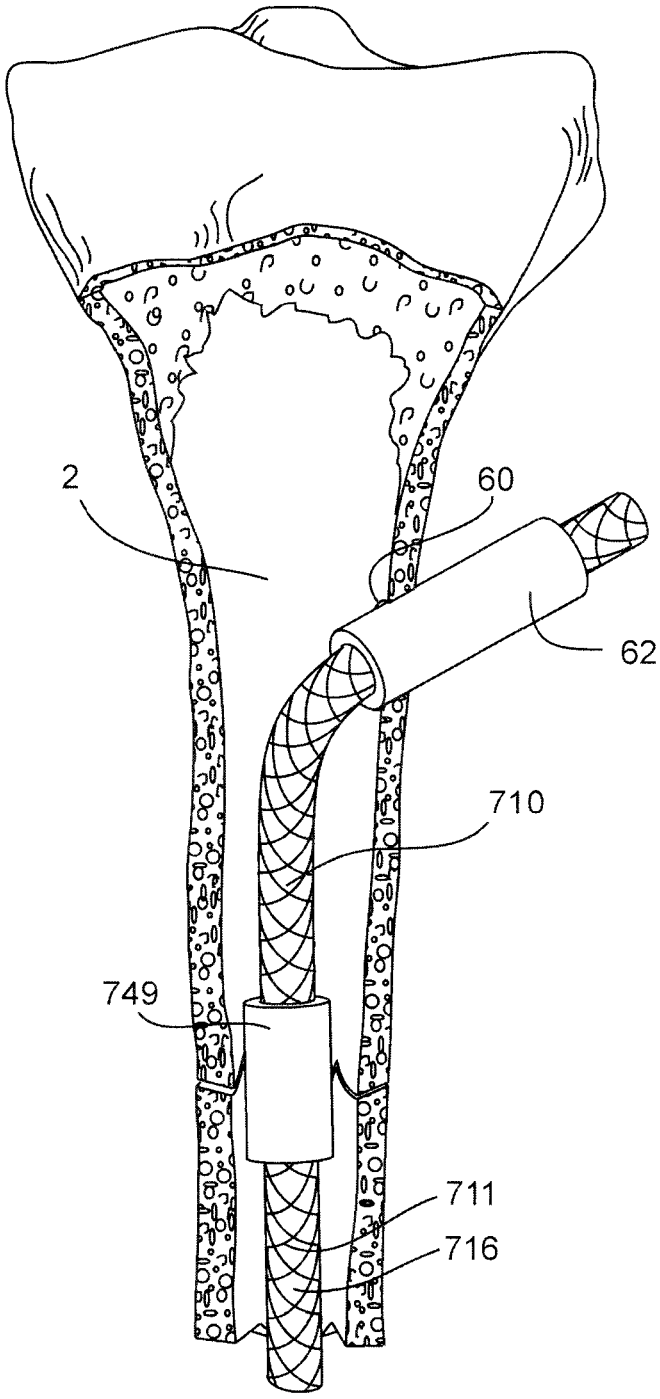
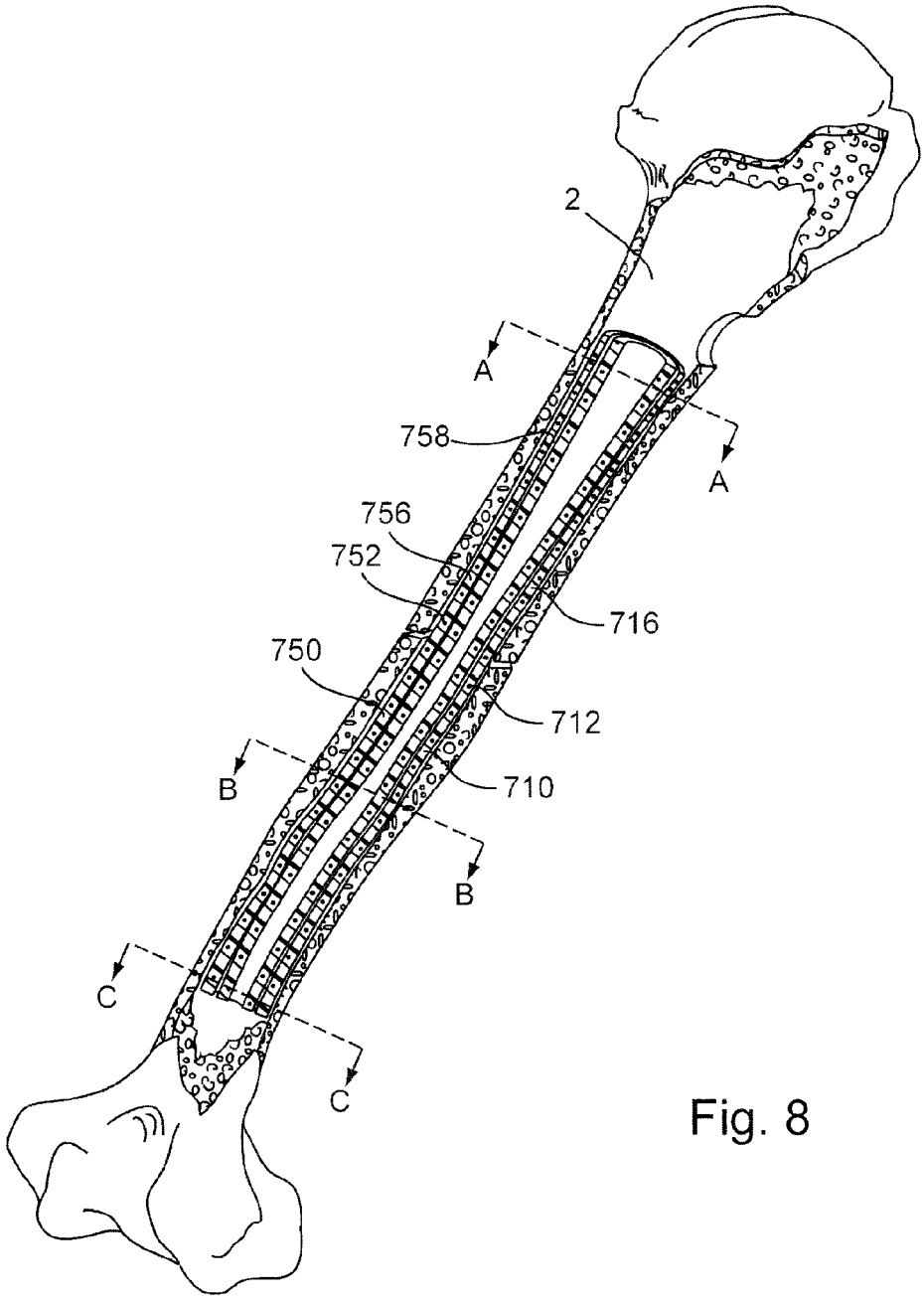


Fig. 7



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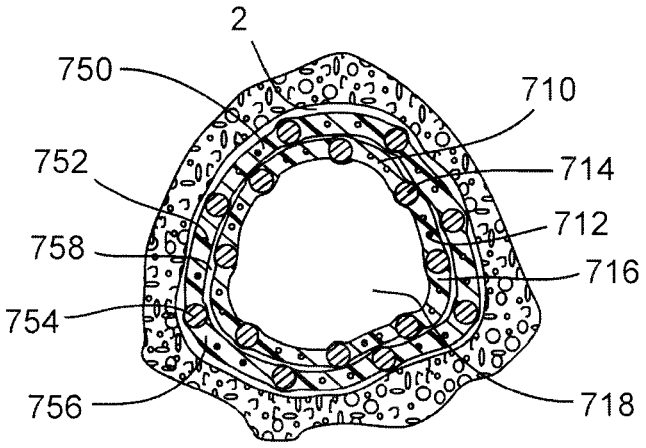
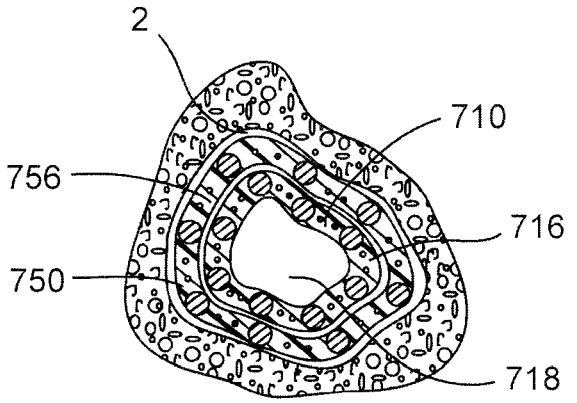


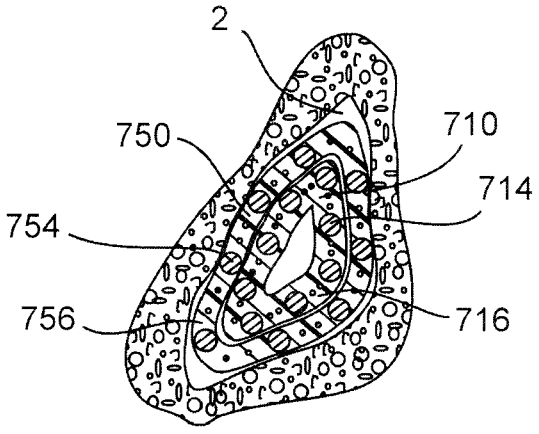
A-A

Fig. 9A



B-B

Fig. 9B



C-C

Fig. 9C

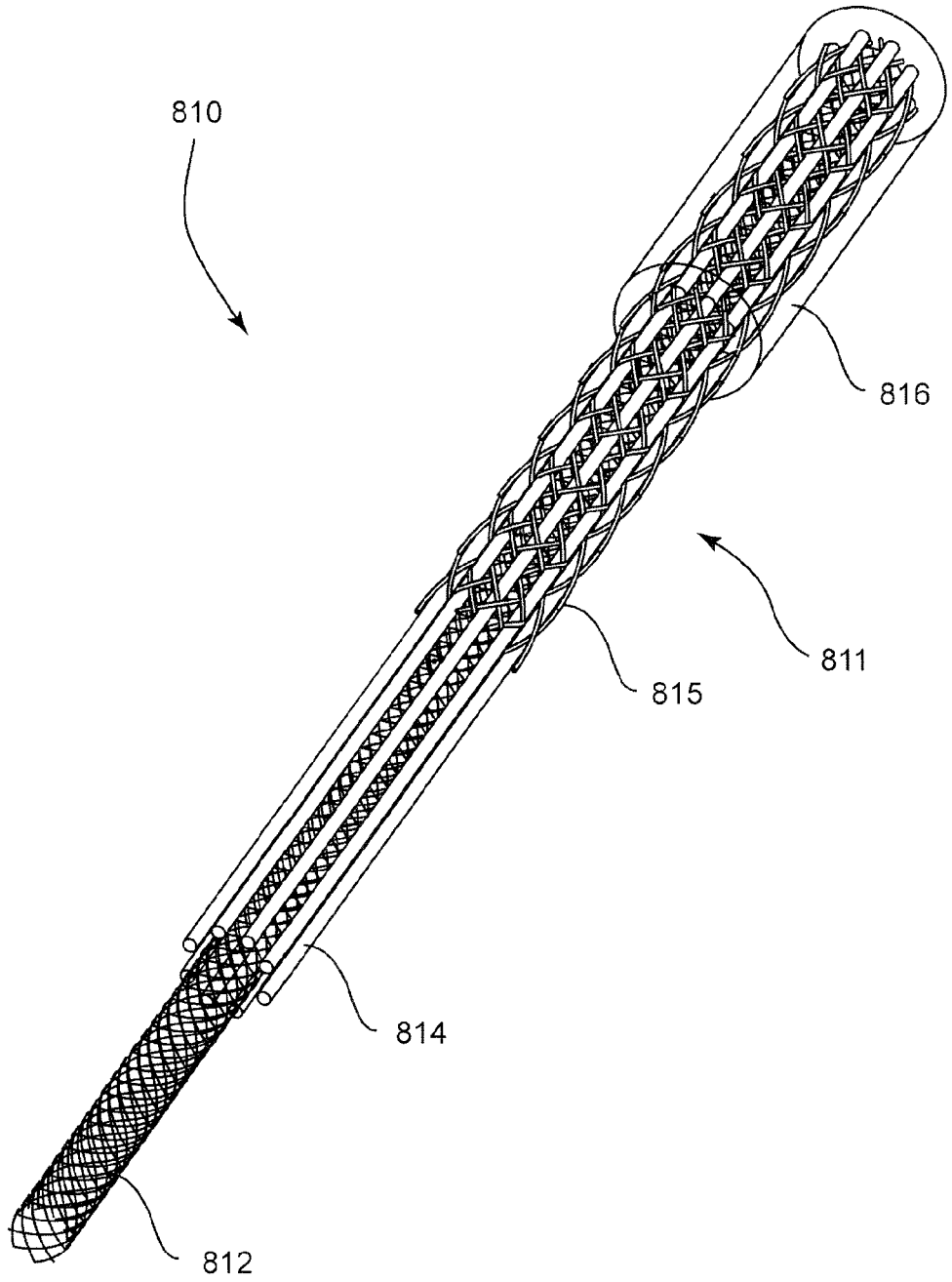


Fig. 10

Fig. 11E

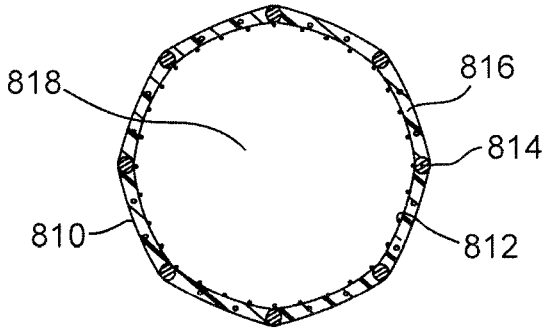


Fig. 11D

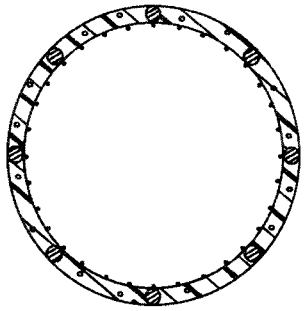


Fig. 11C

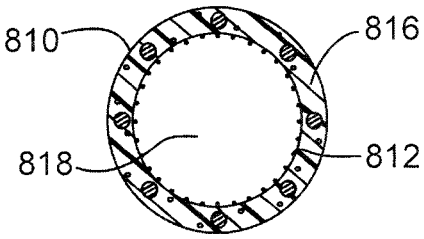


Fig. 11B

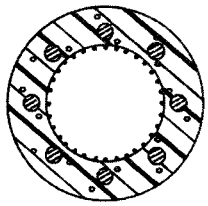
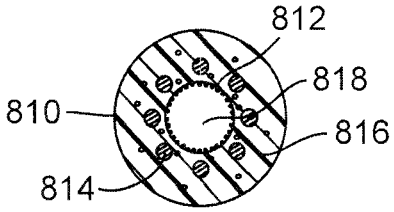


Fig. 11A



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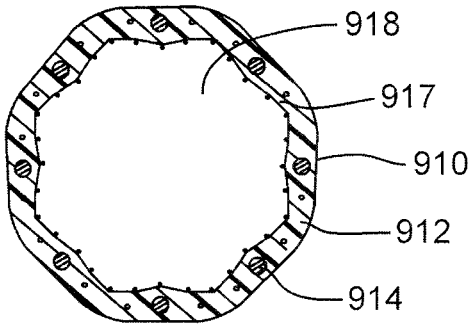

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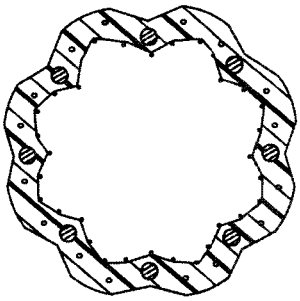


Fig. 12C

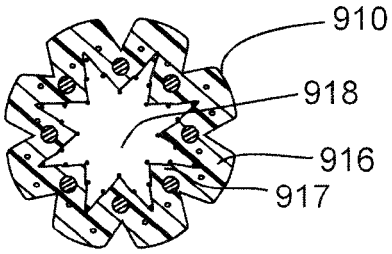


Fig. 12B

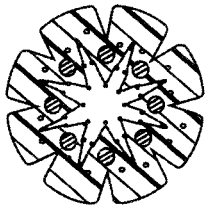
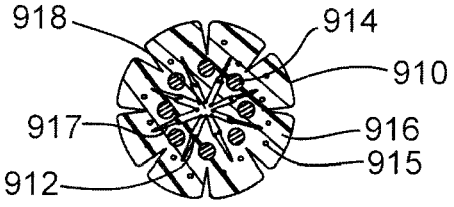


Fig. 12A



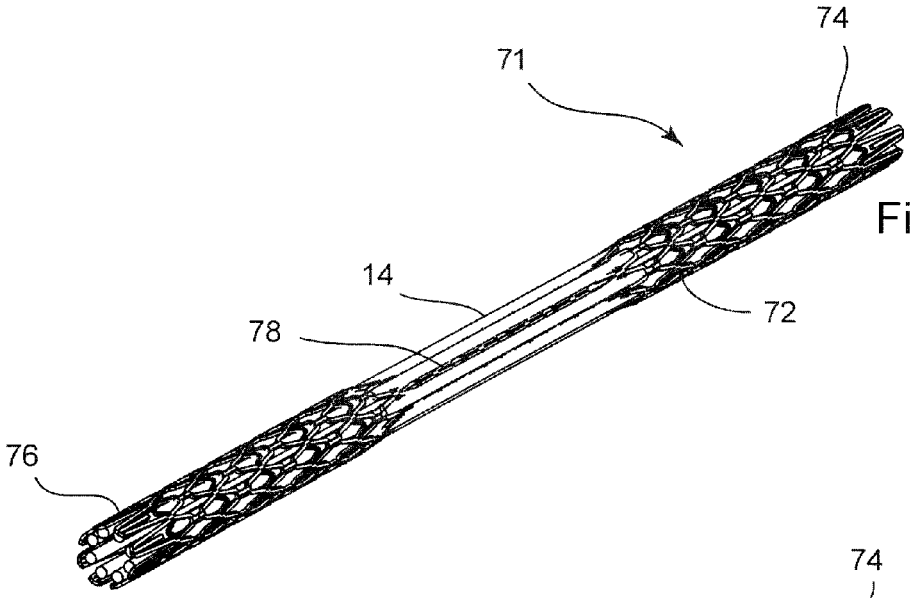


Fig. 13A

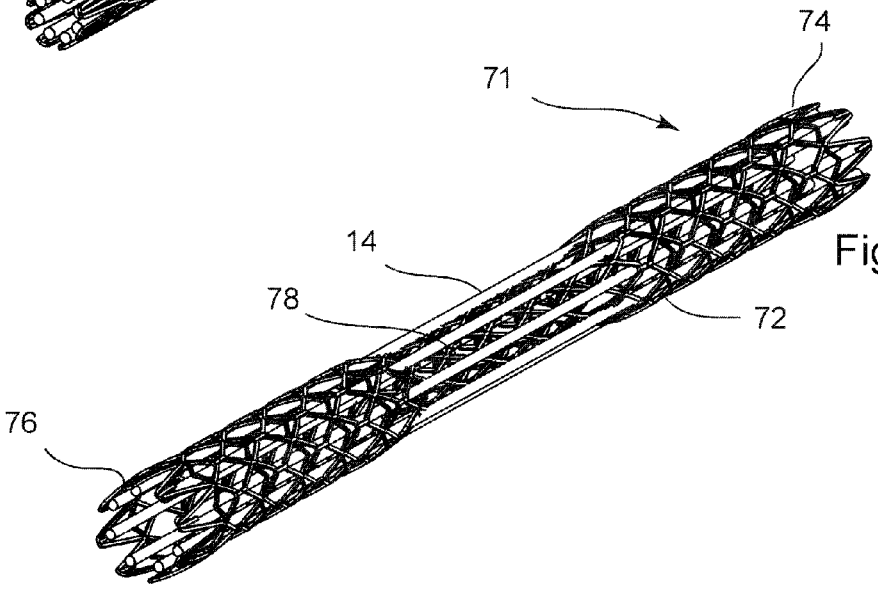


Fig. 13B

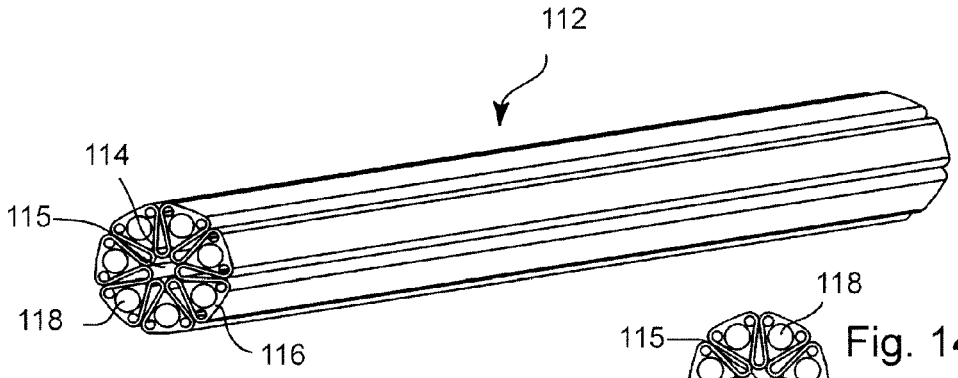


Fig. 14A

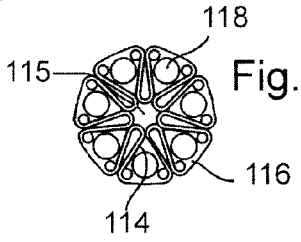


Fig. 14B

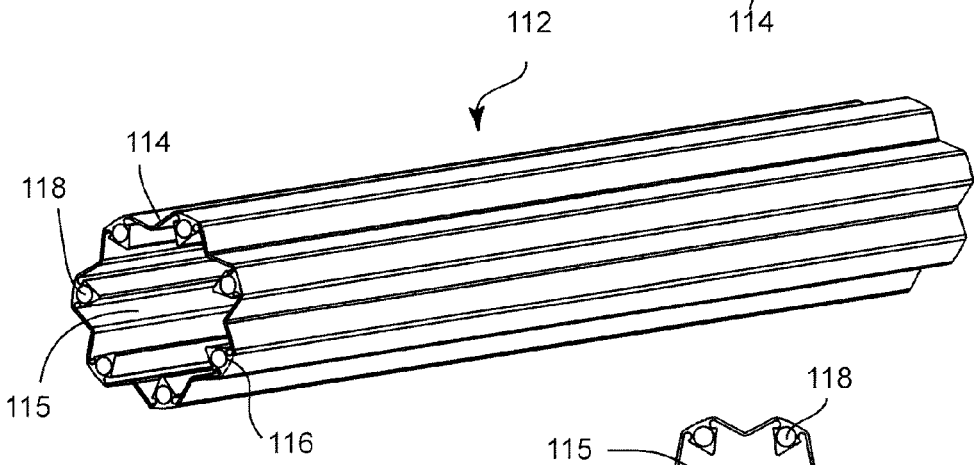


Fig. 14C

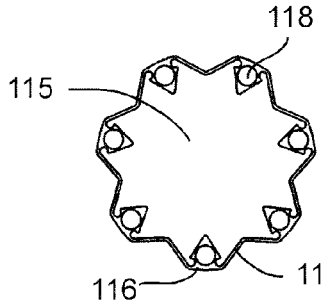


Fig. 14D

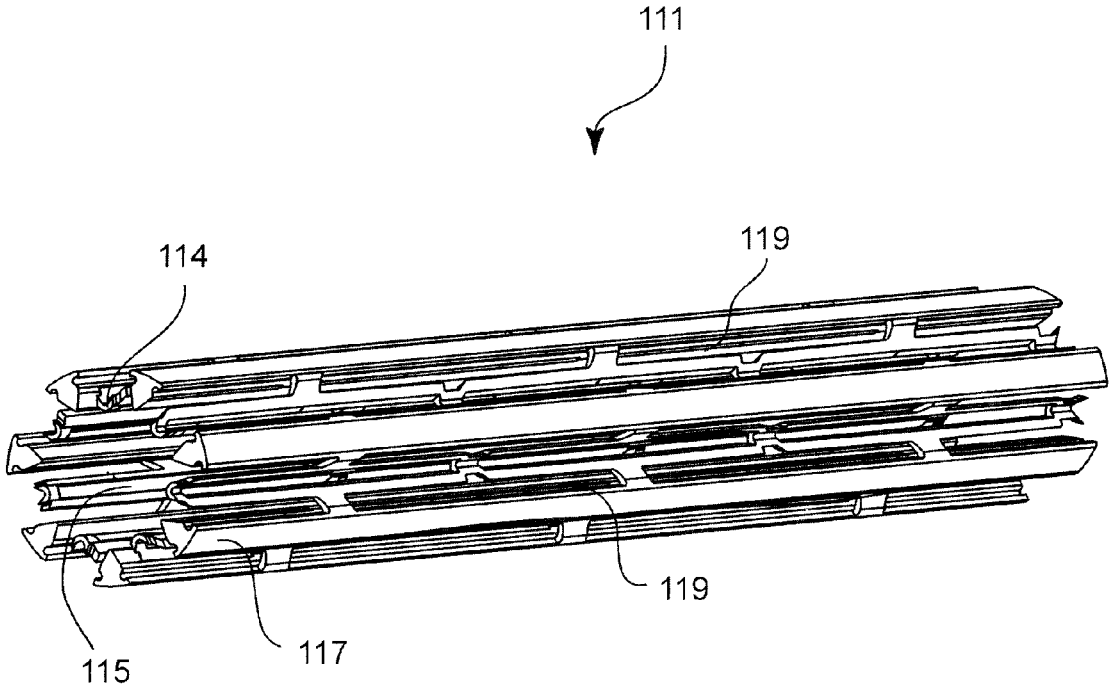


Fig. 15

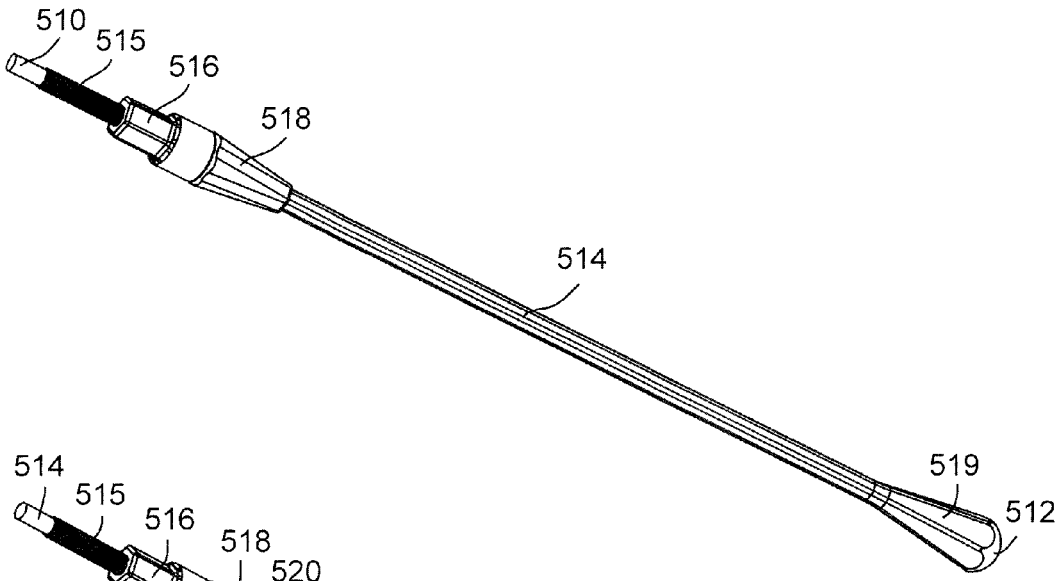


Fig. 16A

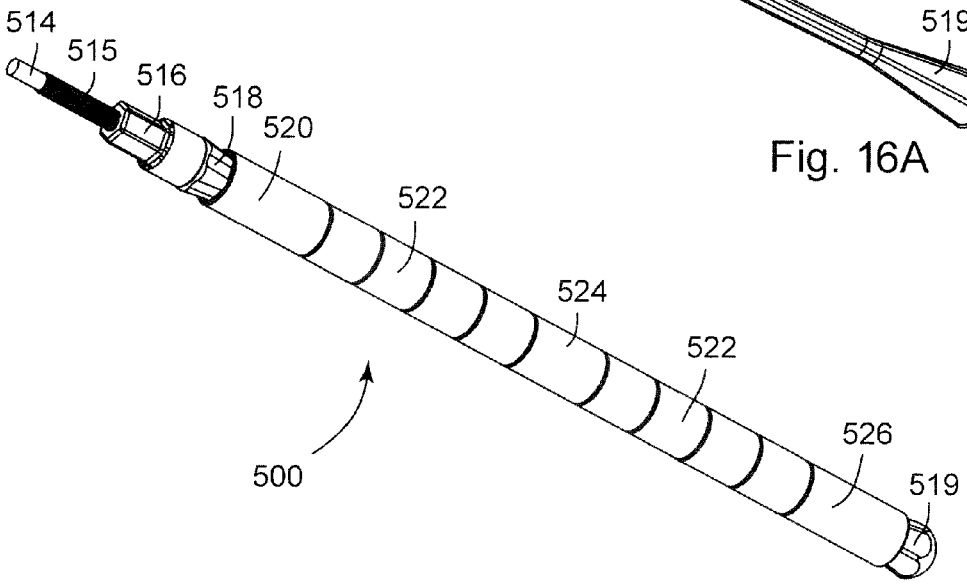
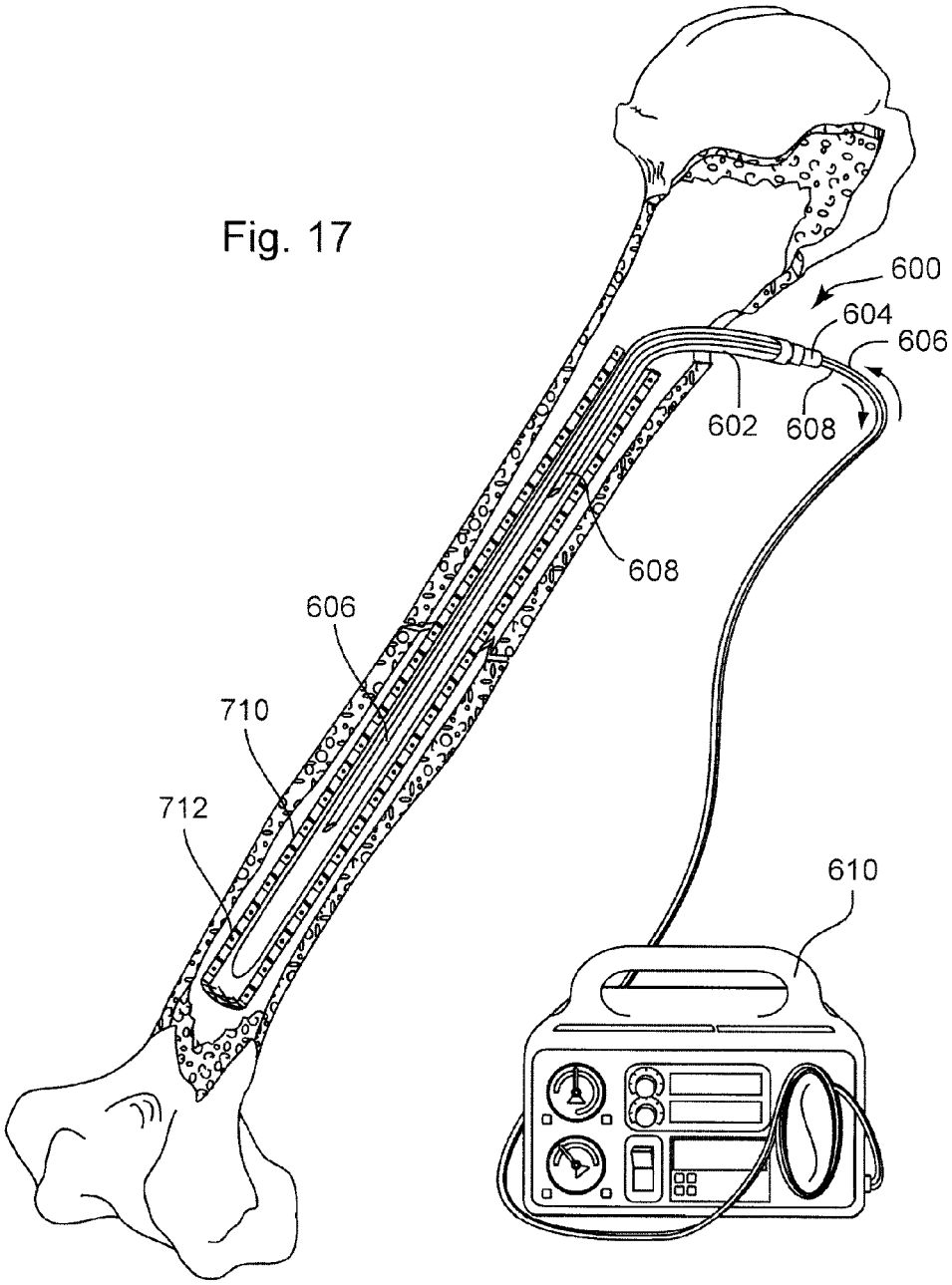


Fig. 16B

Fig. 17



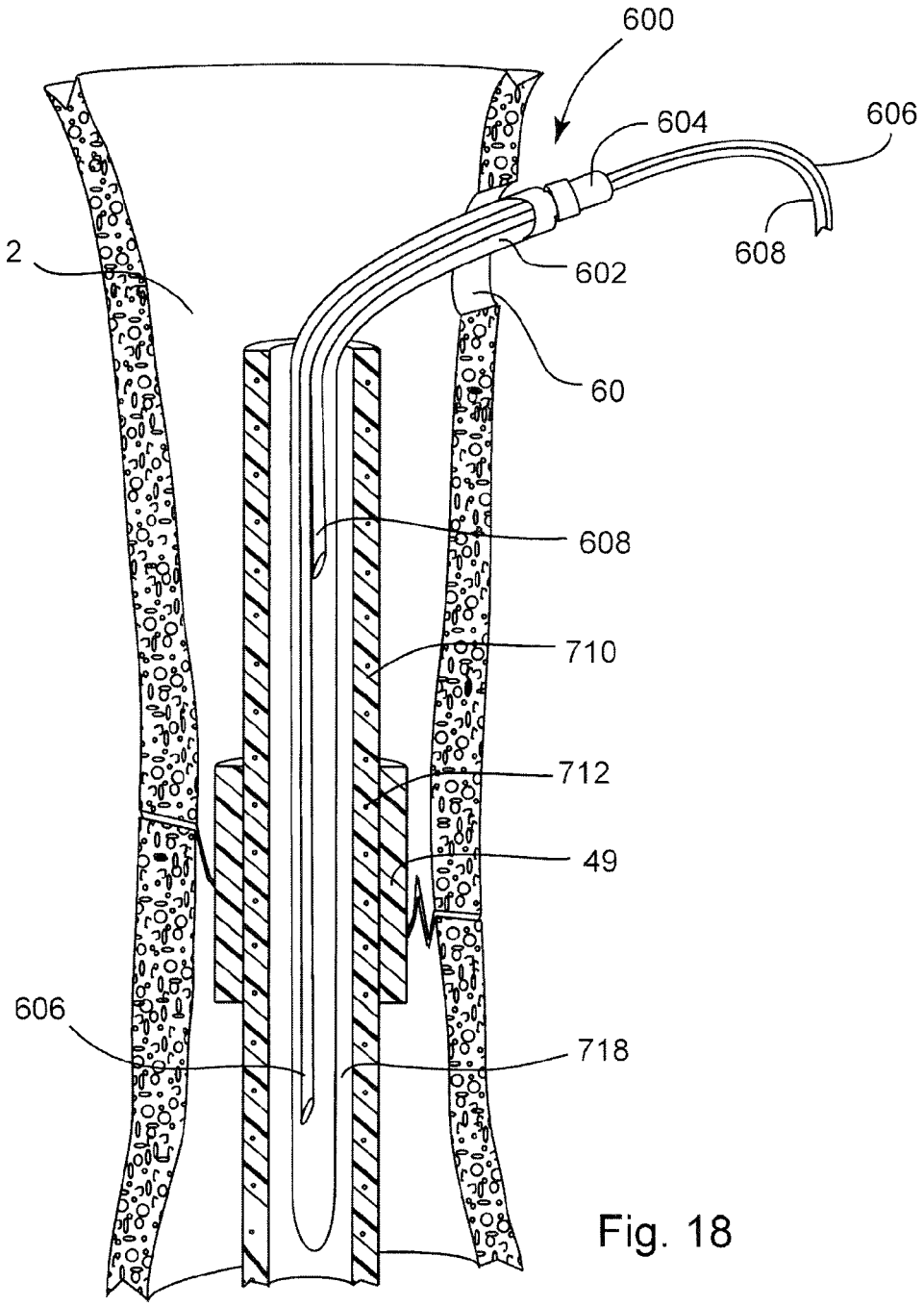


Fig. 18

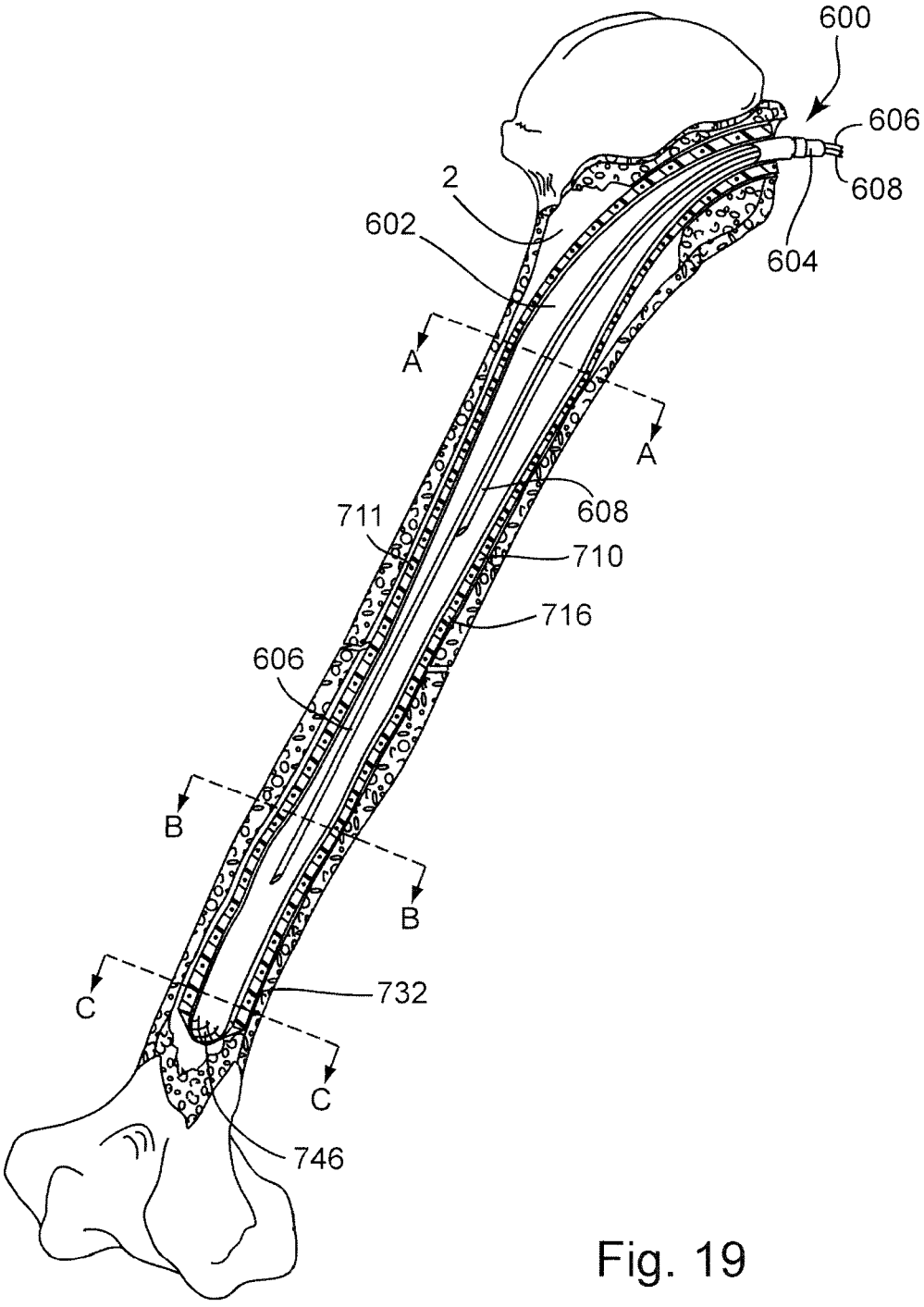
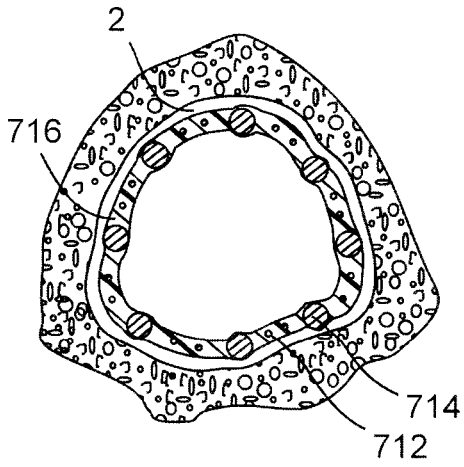
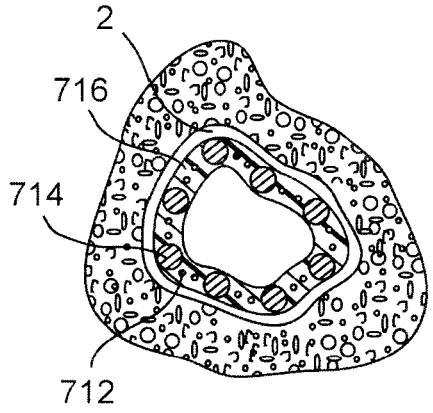


Fig. 19



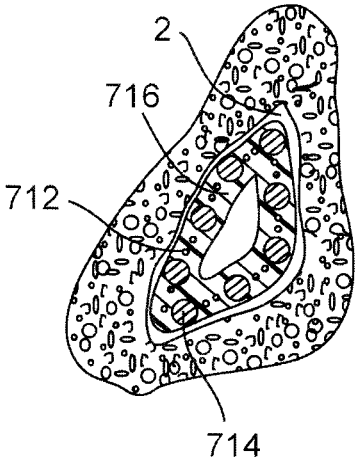
A-A

Fig. 20A



B-B

Fig. 20B



C-C

Fig. 20C

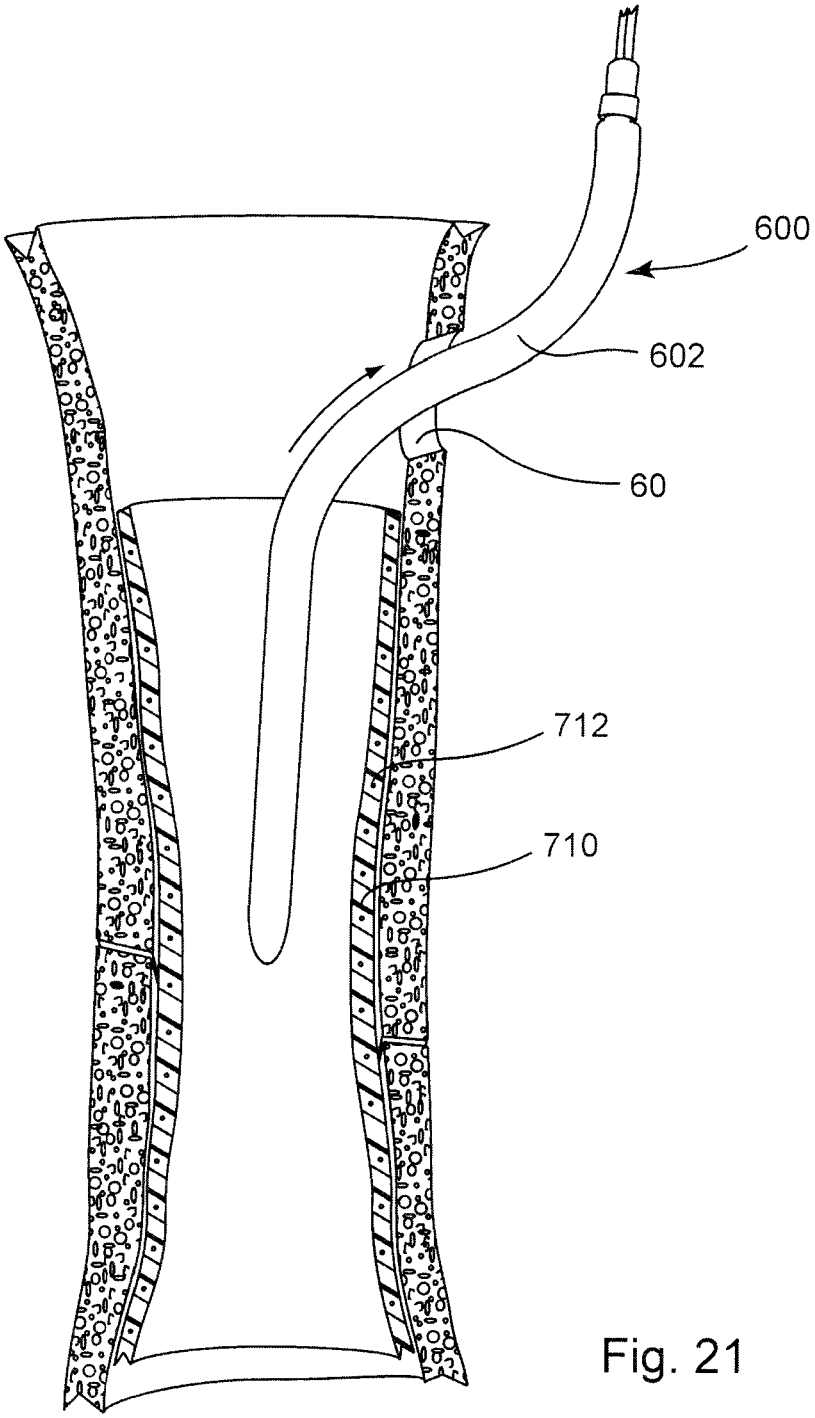


Fig. 21

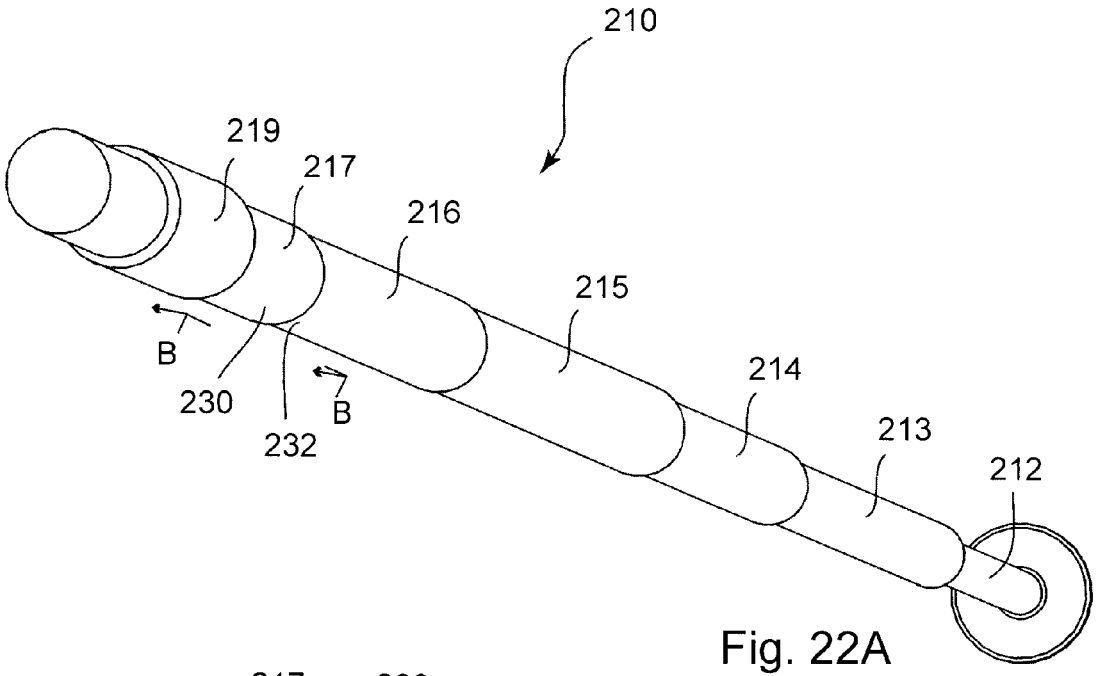


Fig. 22A

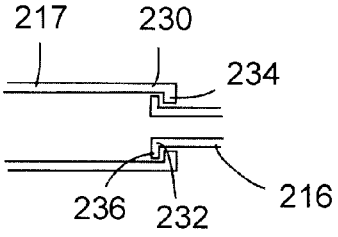


Fig. 22B

B-B

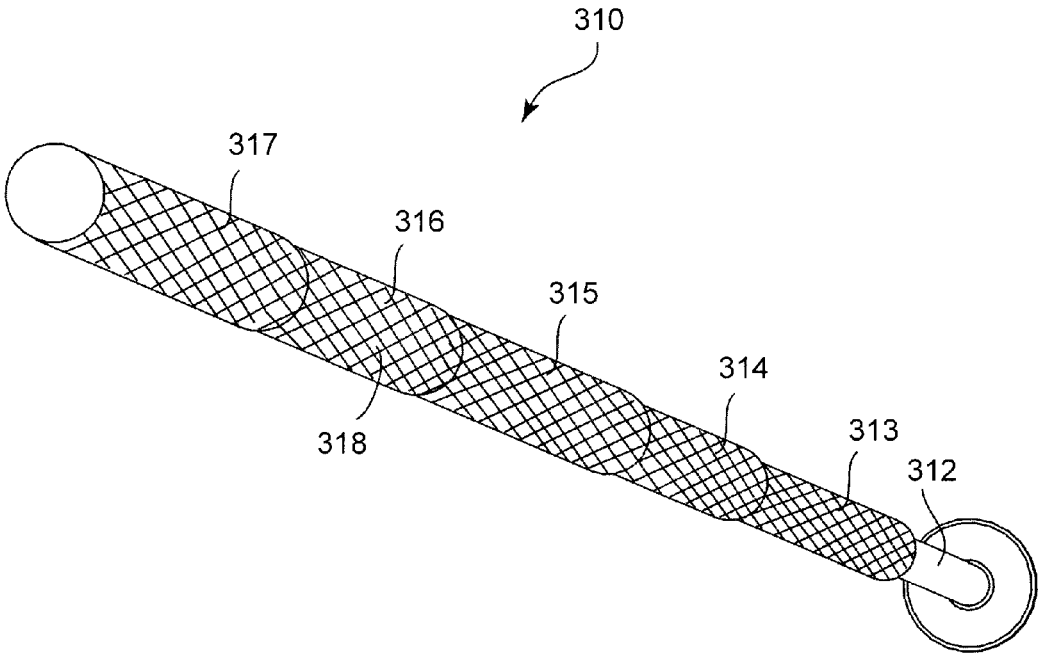


Fig. 23

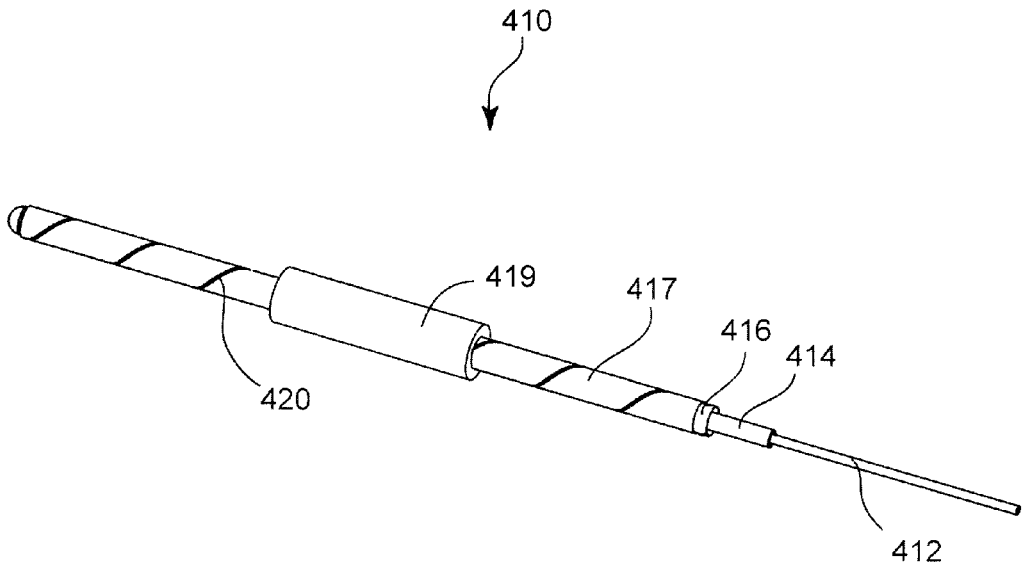


Fig. 24

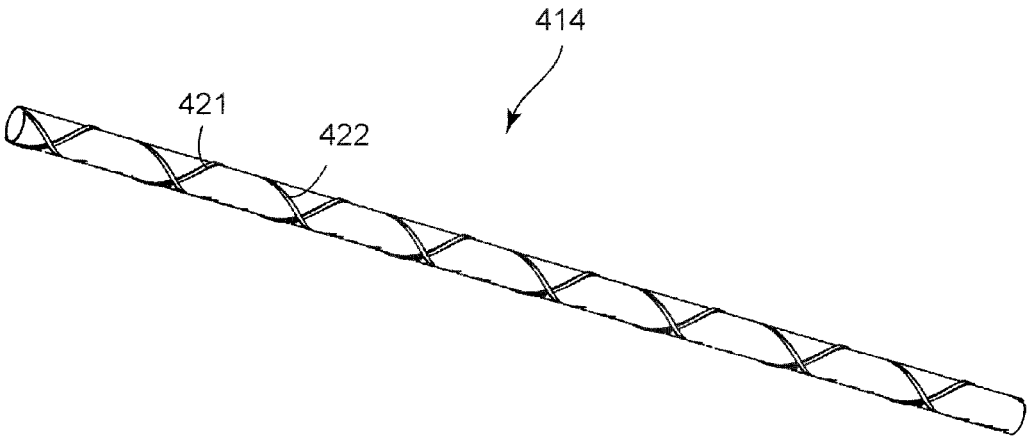


Fig. 25A

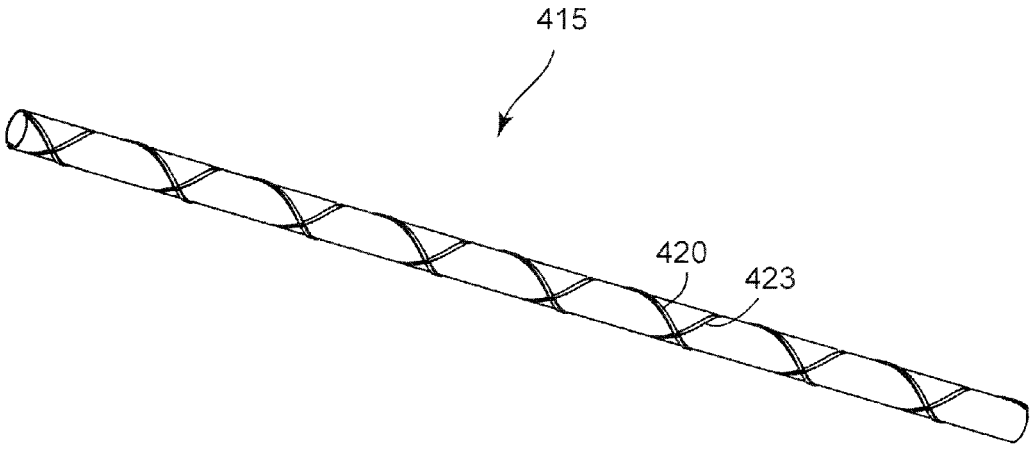


Fig. 25B

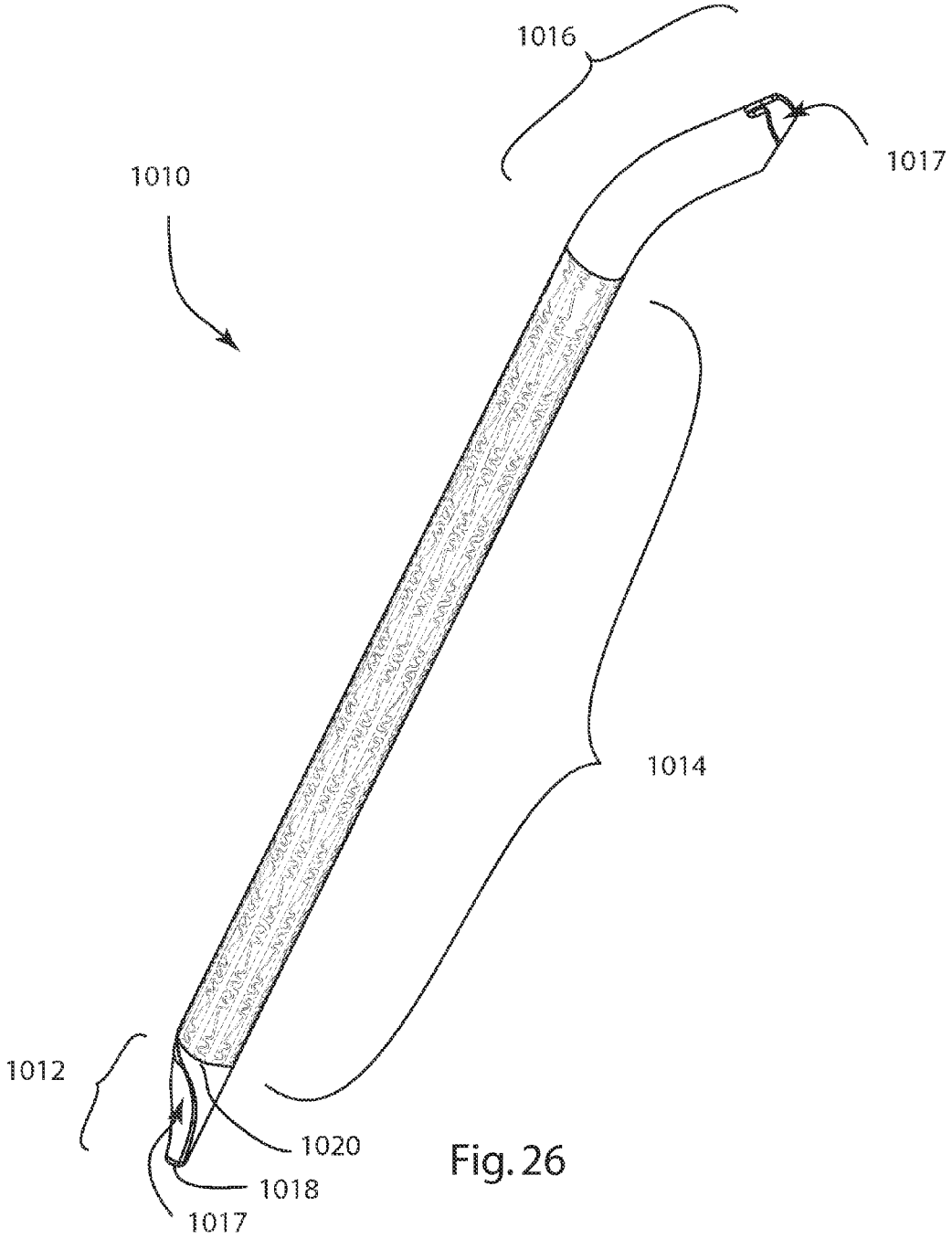


Fig. 26

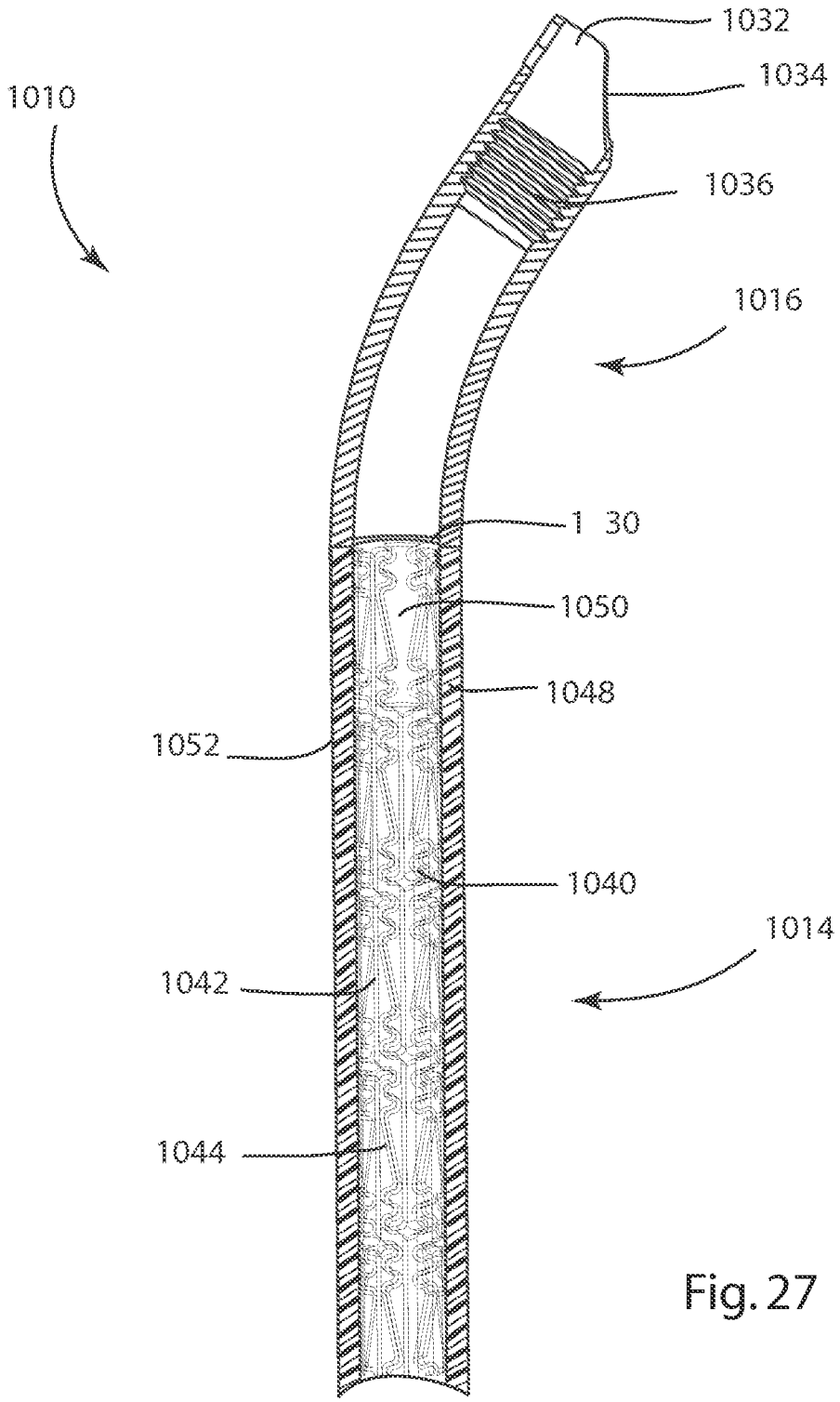

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Fig. 27

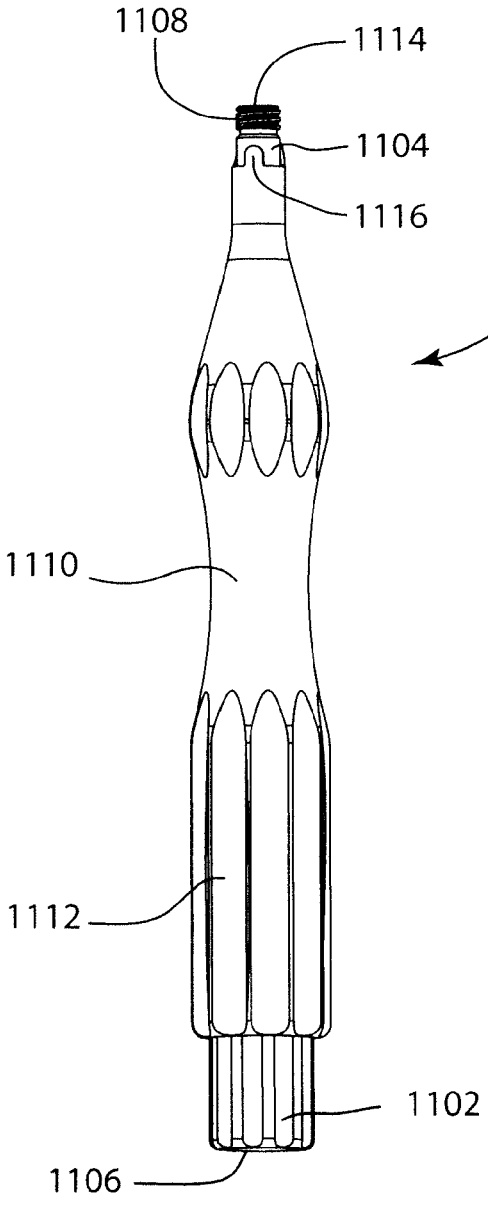

Fig. 28A

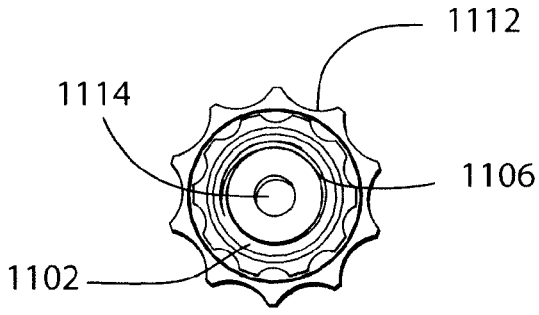

Fig. 28B

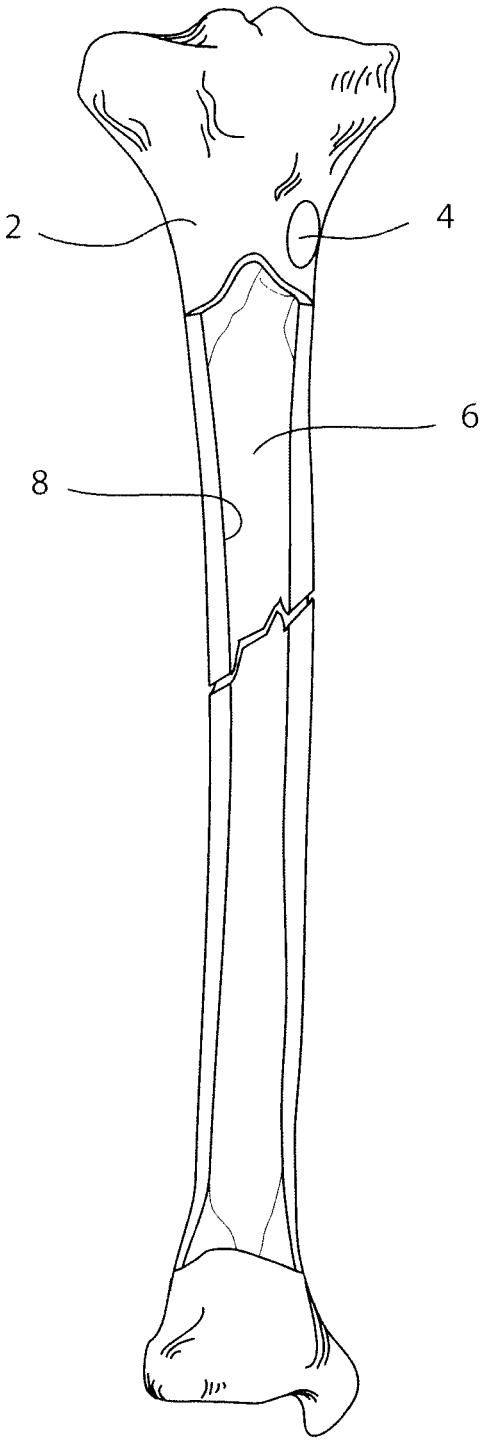

Fig. 29

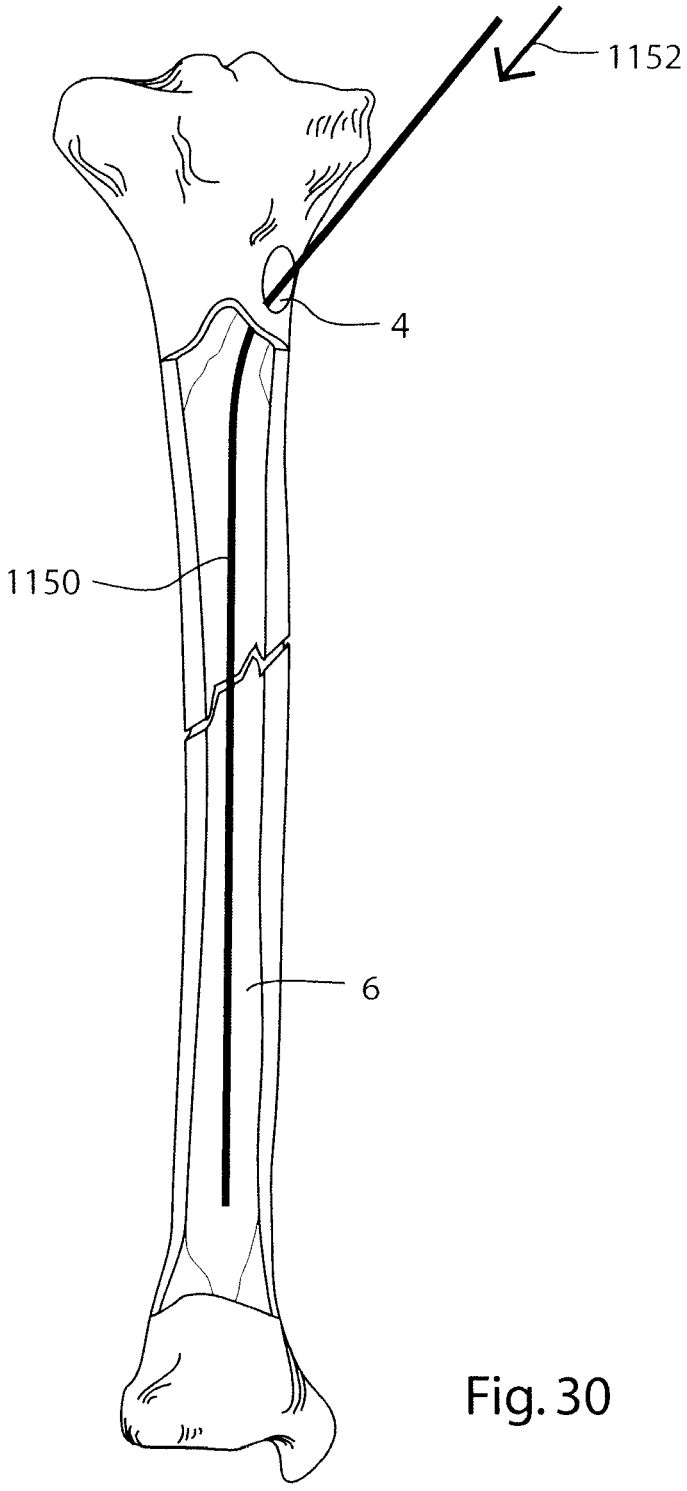

Fig. 30

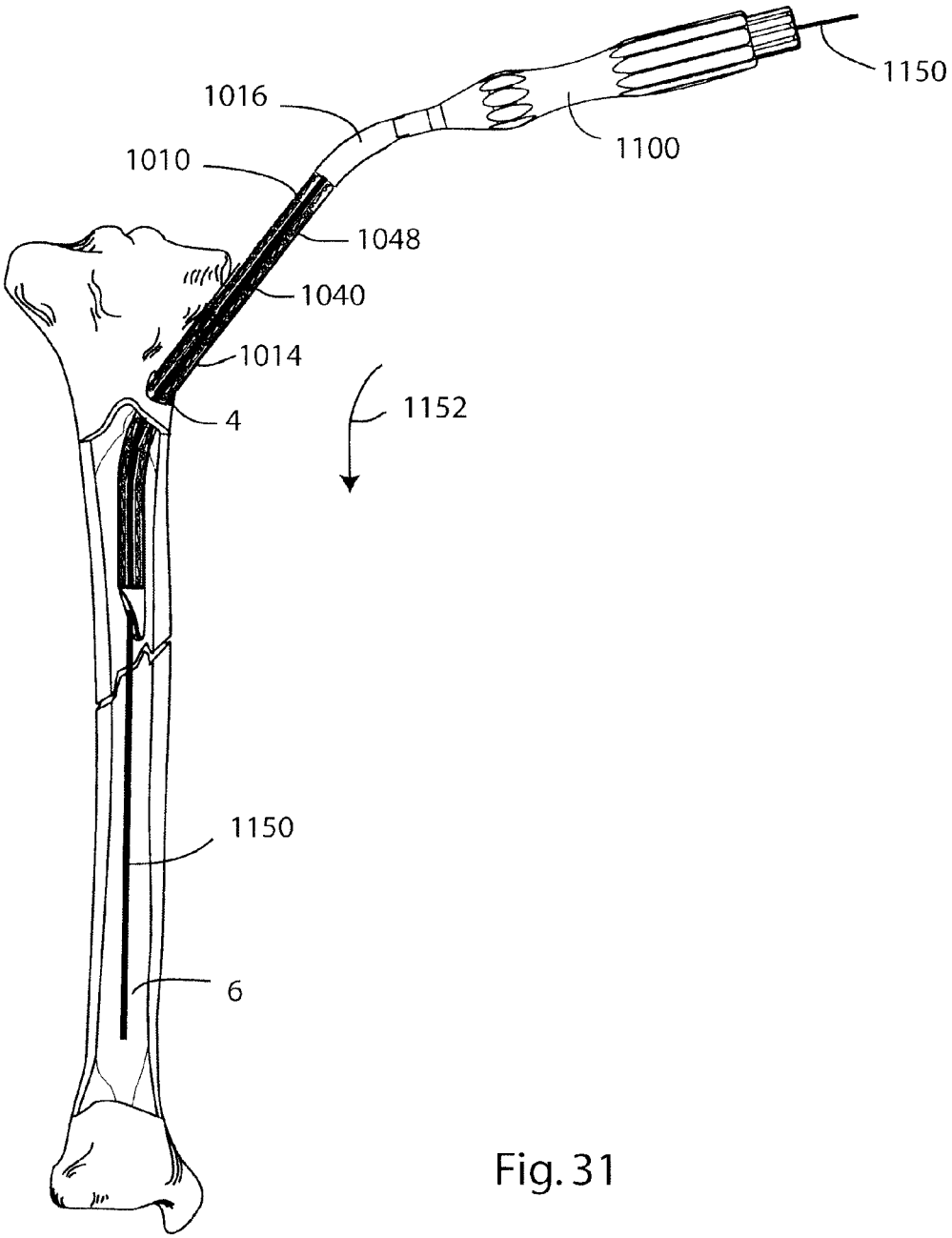

Fig. 31

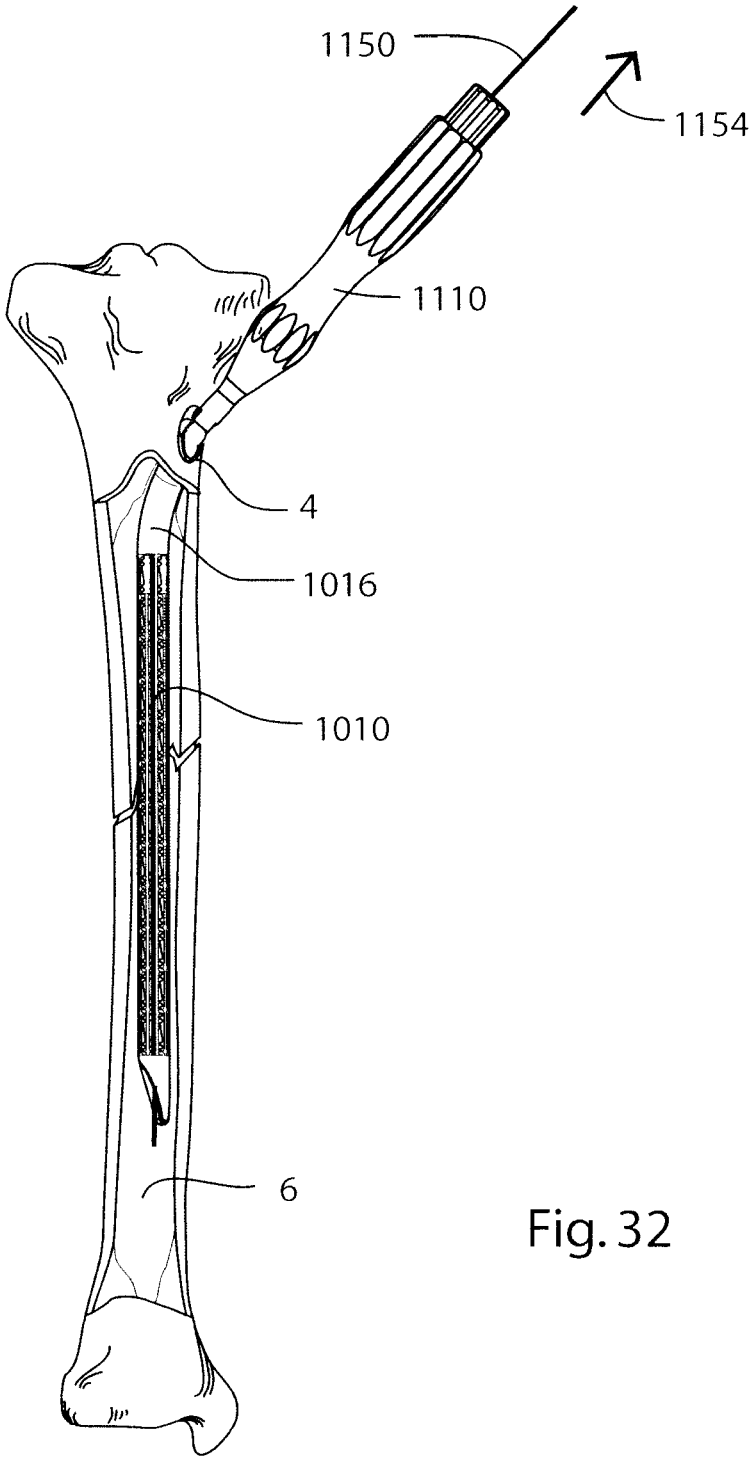

Fig. 32

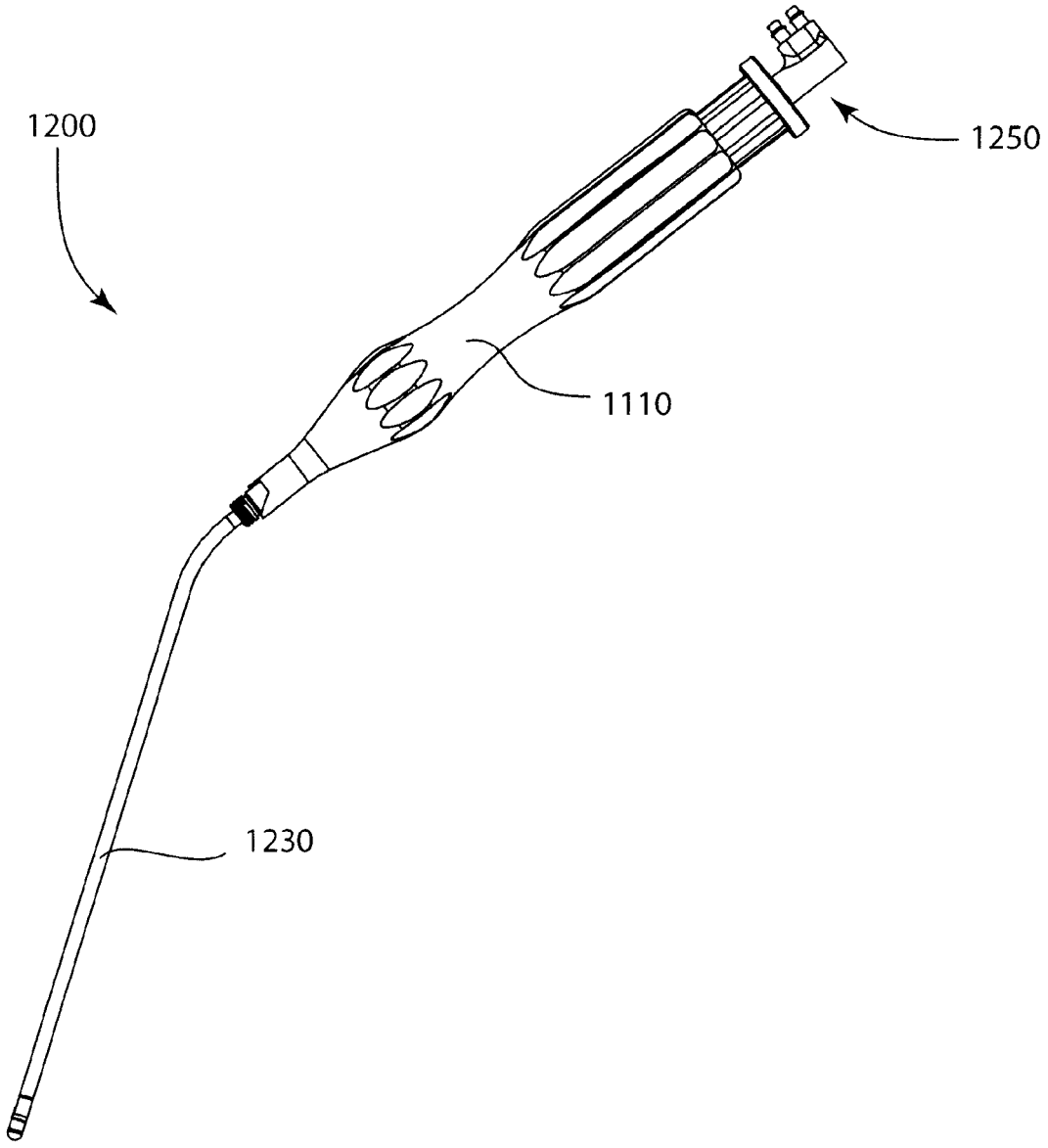

Fig. 33

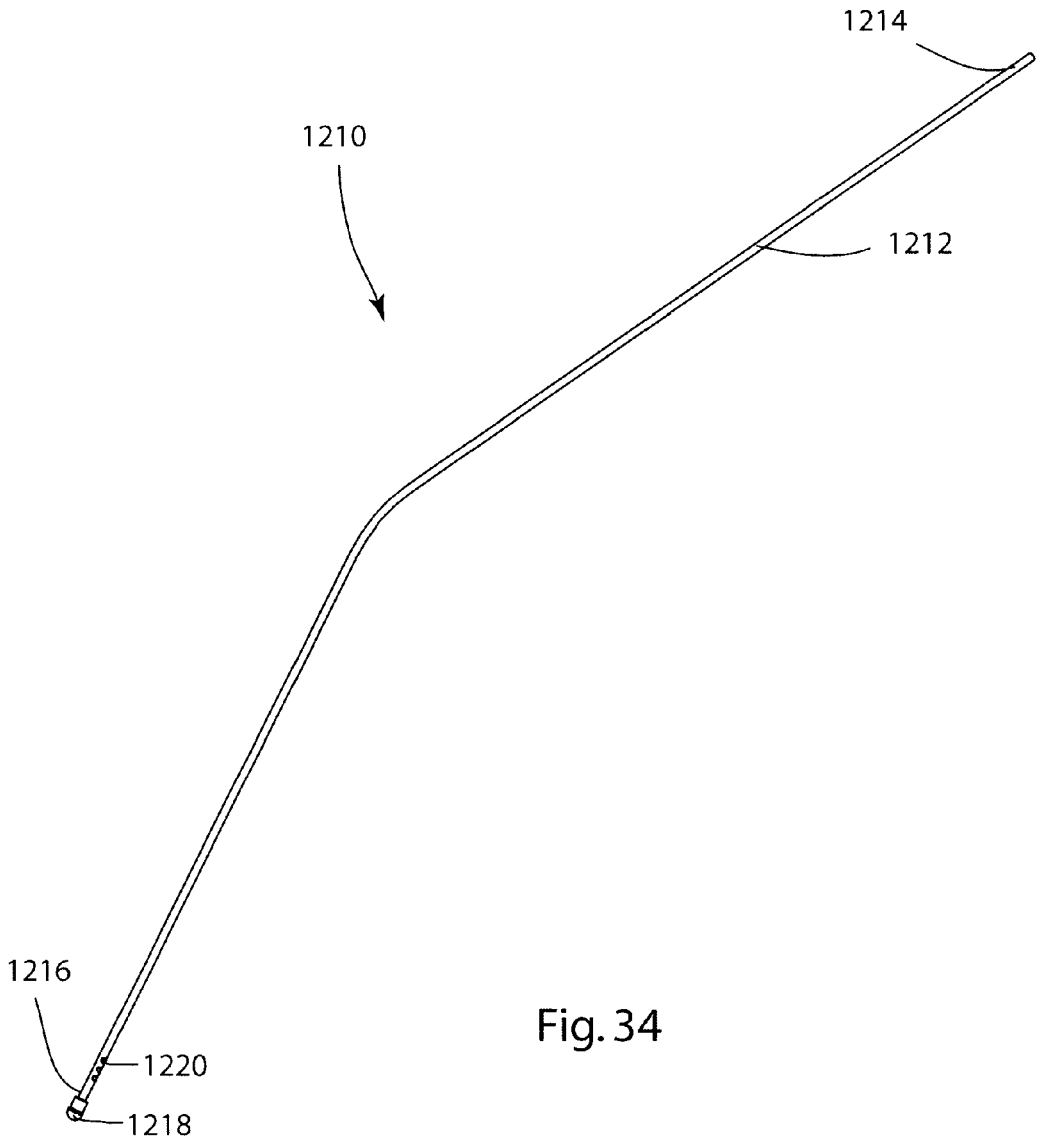

Fig. 34

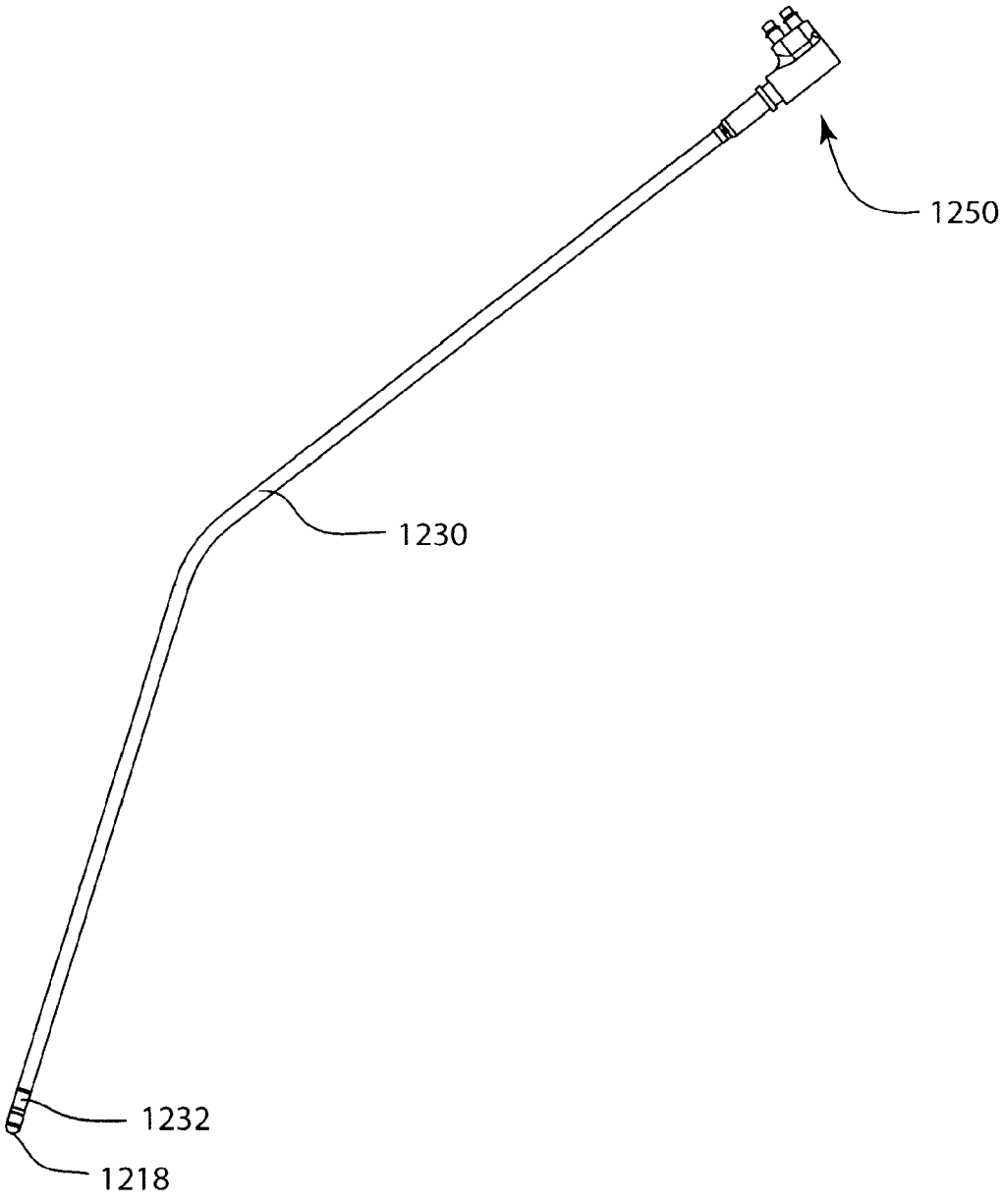

Fig. 35

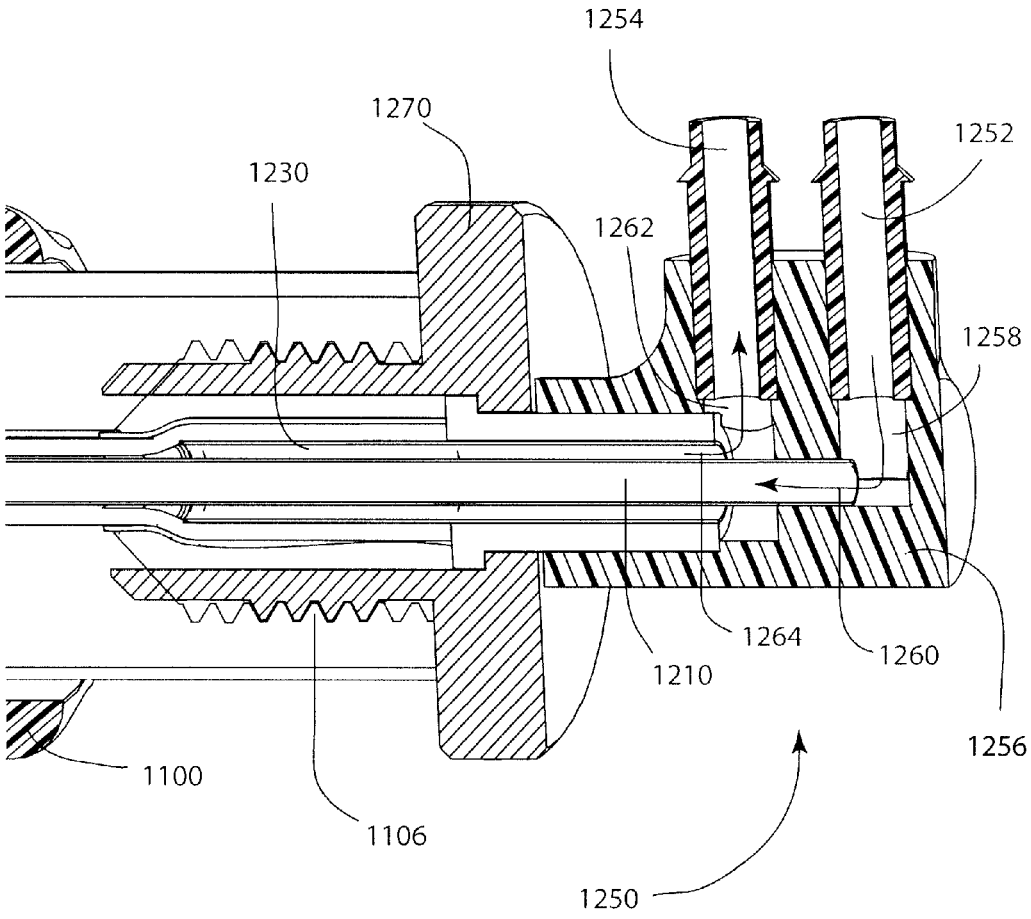
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Fig. 36

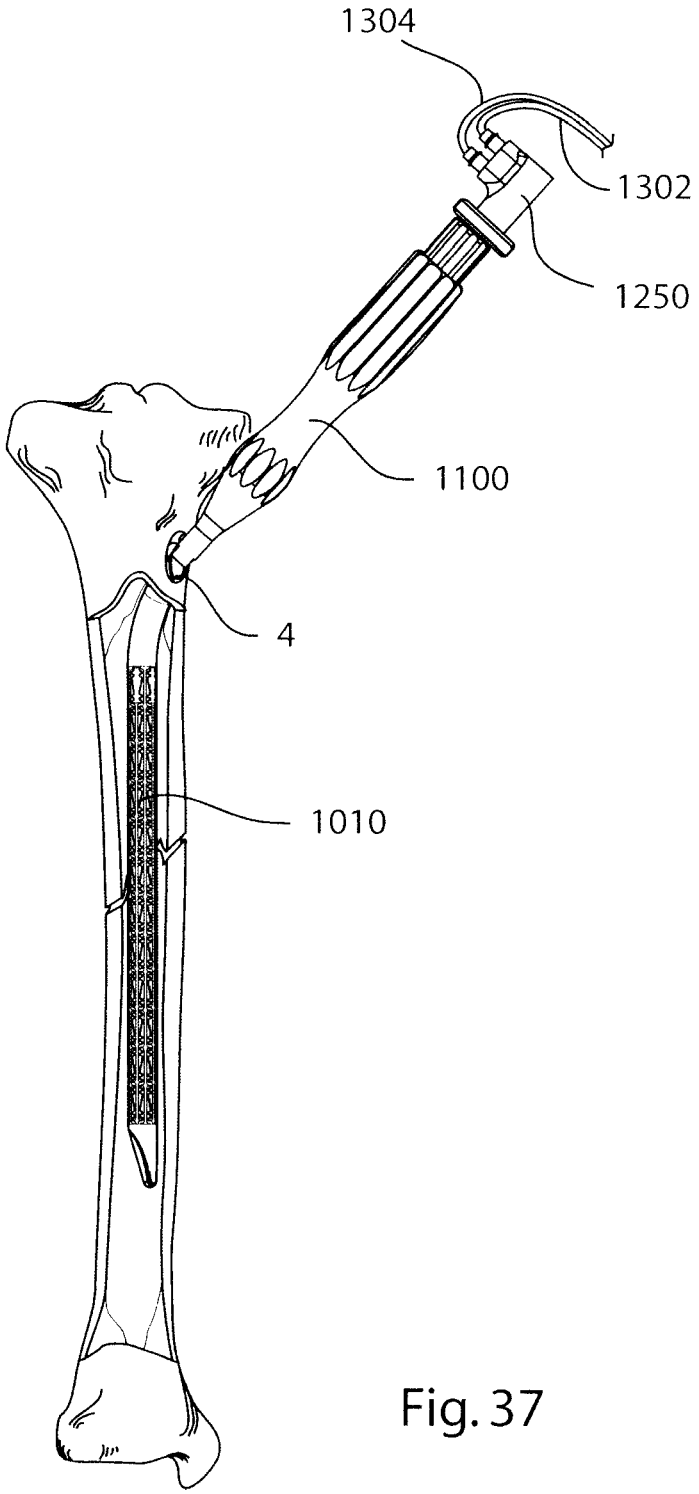

Fig. 37

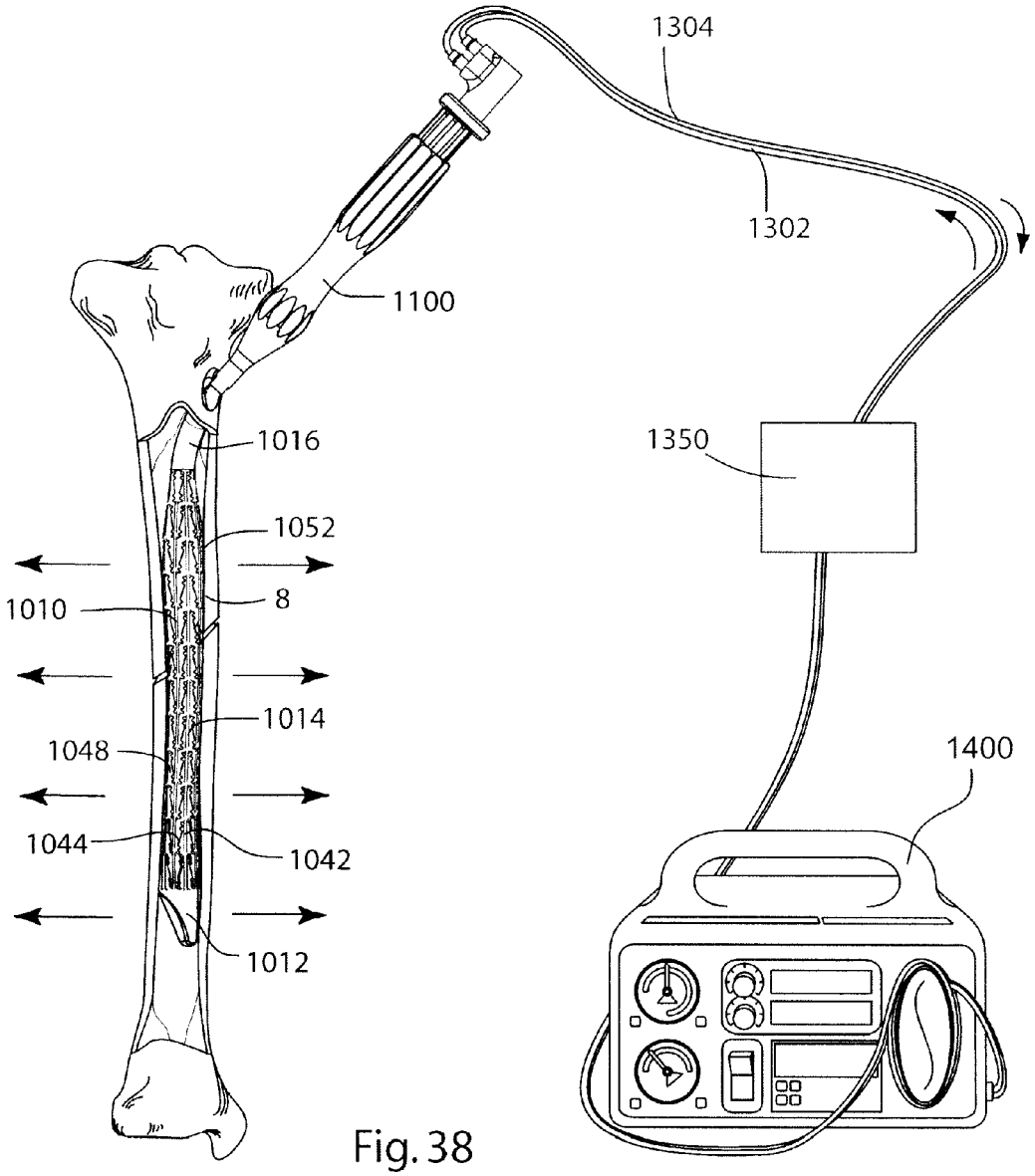
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Fig. 38

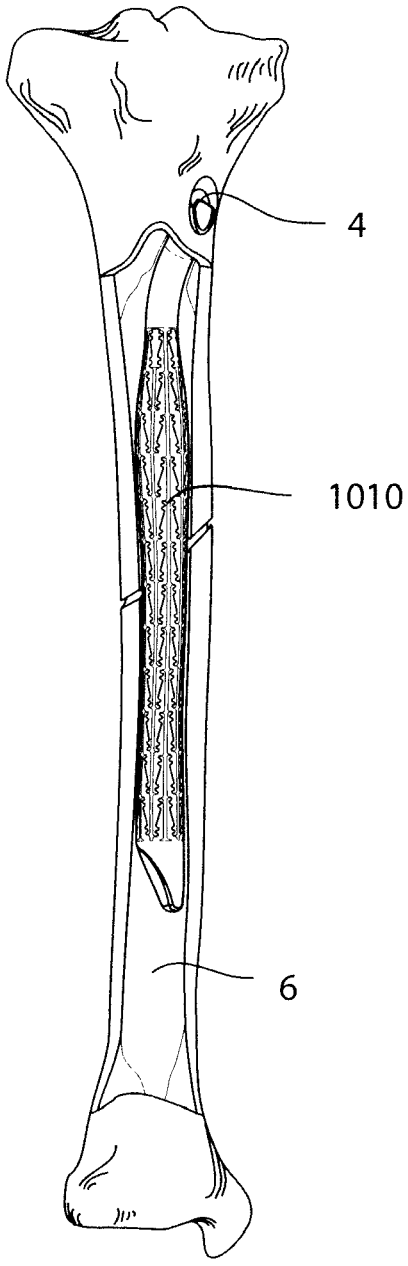

Fig. 39

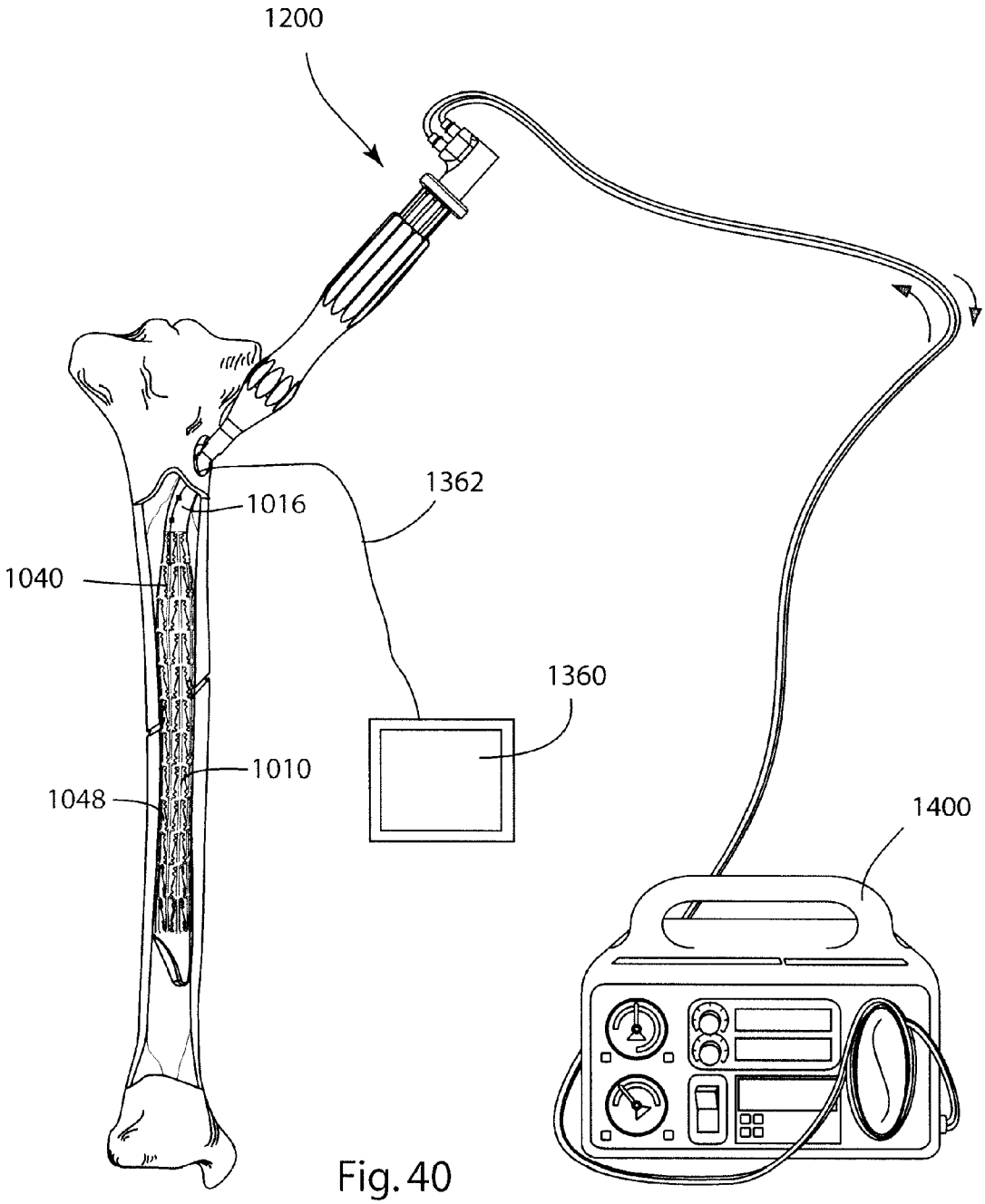

Fig. 40

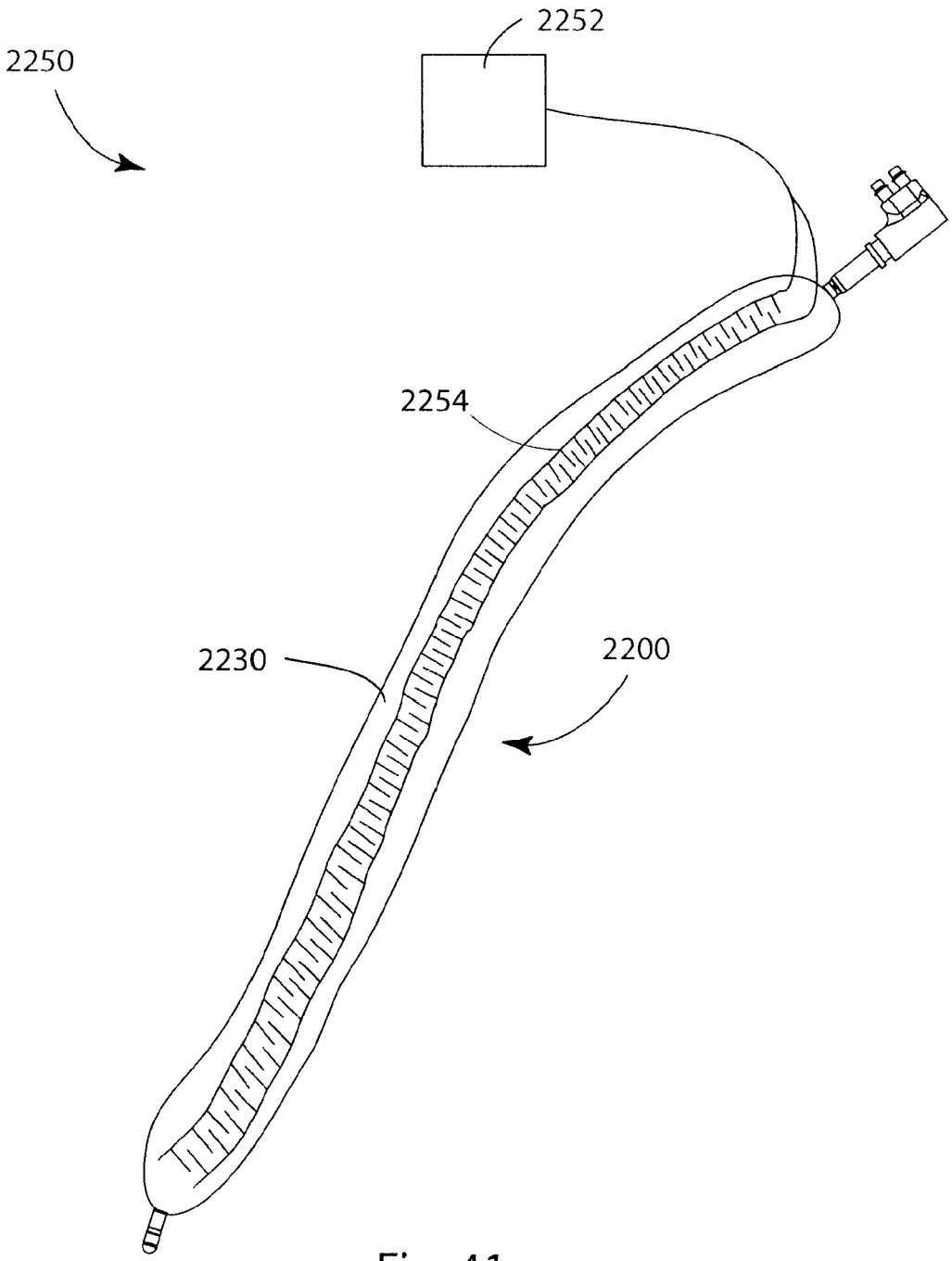

Fig. 41

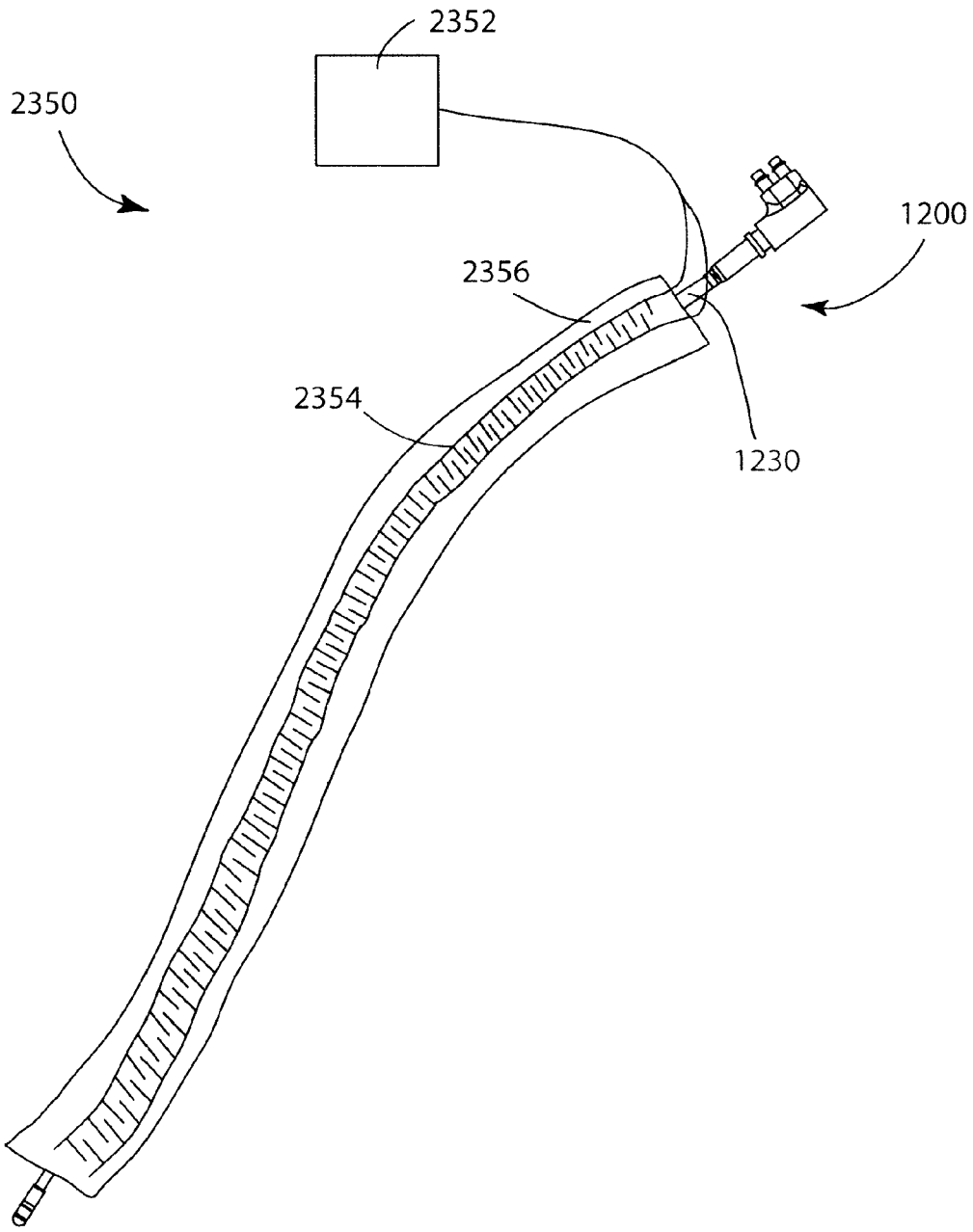

Fig. 42

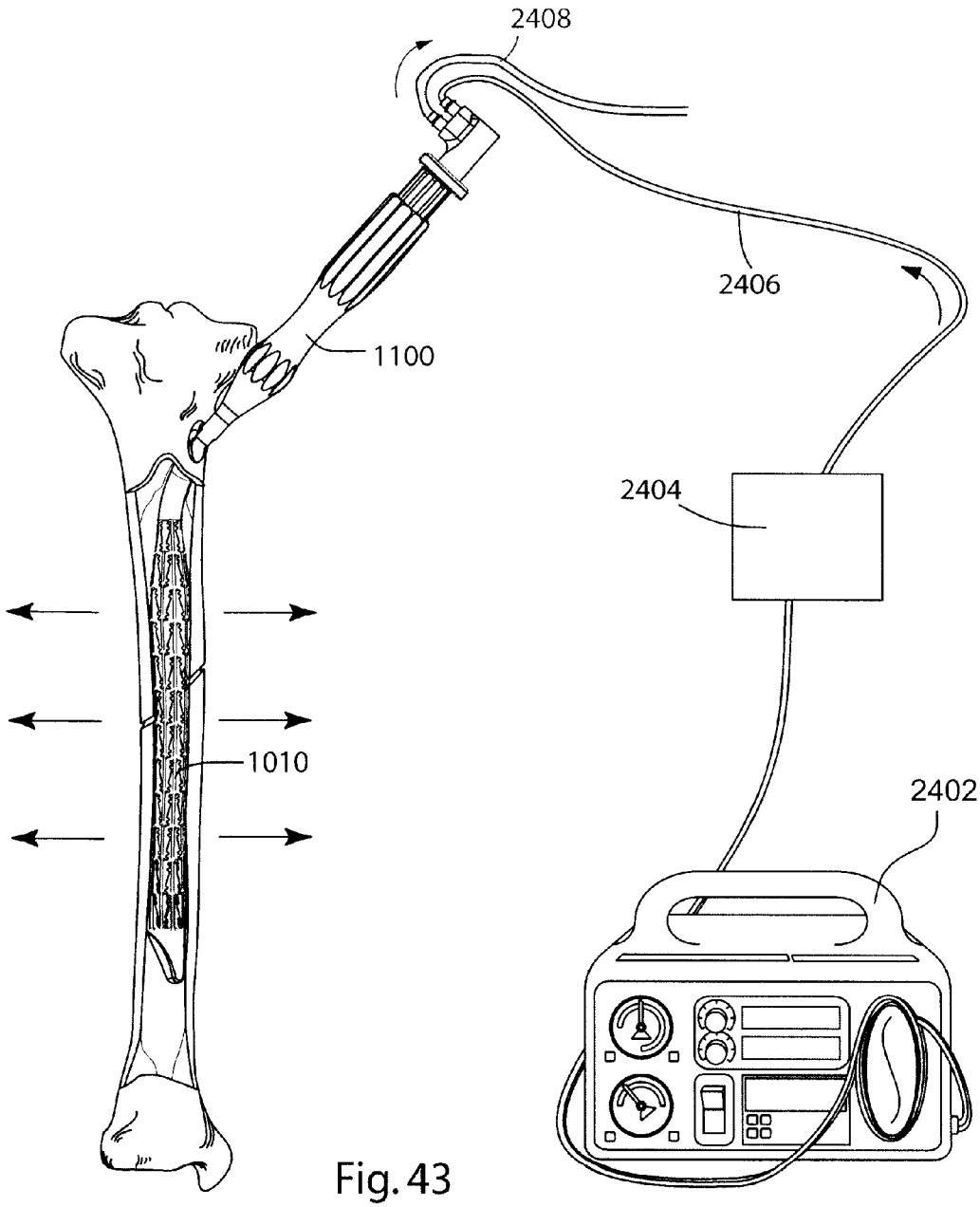

Fig. 43

BONE STABILIZATION DEVICE AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 13/423,914, filed Mar. 19, 2012, Entitled BONE STABILIZATION DEVICE AND METHOD, which is a continuation of U.S. application Ser. No. 12/027,521, now U.S. Pat. No. 8,167,881, filed Feb. 7, 2008, entitled IMPLANTABLE COMPOSITE APPARATUS, which is a continuation in part of U.S. patent application Ser. No. 11/777,846, filed Jul. 13, 2007, entitled THERMO-CHEMICALLY ACTIVATED INTRAMEDULLARY BONE STENT; and U.S. patent application Ser. No. 11/777,872, filed Jul. 13, 2007, entitled CONFORMABLE INTRAMEDULLARY IMPLANT WITH NESTABLE COMPONENTS; and U.S. patent application Ser. No. 11/777,892, now U.S. Pat. No. 8,128,626, filed Jul. 13, 2007, entitled SYSTEM AND METHOD FOR DELIVERY, CONFORMATION AND REMOVAL OF INTRAMEDULLARY BONE FIXATION DEVICES; each of which claims the benefit of U.S. Provisional Patent Application No. 60/913,696, filed Apr. 24, 2007 entitled THERMOCHEMICALLY ACTIVATED INTRAMEDULLARY BONE STENT; all of these patent applications being incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. The Field of the Invention

The present invention relates generally to orthopedic devices for the surgical treatment of bone and, more particularly, to the stabilization of bones with an intramedullary device.

2. The Relevant Technology

Orthopedic medicine provides a wide array of implants that can be attached to bone to repair fractures. External fixation involves the attachment of a device that protrudes out of the skin, and therefore carries significant risk of infection. May fractures in long bones can be repaired through the use of bone plates, which are implanted and attached to lie directly on the bone surface. The bone plate then remains in the body long enough to allow the fractured bone to heal properly. Unfortunately, such bone plates often require the surgical exposure of substantially the entire length of bone to which the plate is to be attached. Such exposure typically results in a lengthy and painful healing process, which must often be repeated when the implantation site is again exposed to allow removal of the plate. There is a need in the art for implants and related instruments that do not require such broad exposure of the fractured bone, while minimizing the probability of infection by avoiding elements that must protrude through the skin as the bone heals.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present invention will now be discussed with reference to the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The drawings may not be to scale.

FIG. **1** is a perspective view of an intramedullary bone fixation device according to one embodiment of the invention, comprising a support structure which includes a cage and a plurality of rods, and a thermo-chemically activated thermoplastic matrix;

FIG. **2** is a perspective view of the cage of FIG. **1**;

FIGS. **3**A-**3**I are perspective views of various embodiments of stent portions suitable for incorporation into the support structure of FIG. **2**;

FIG. **4** is an enlarged perspective view of a first end of the cage of FIG. **2**;

FIG. **5** is a perspective view of the rods of FIG. **1**;

FIG. **6** is a perspective view of the thermoplastic matrix of FIG. **1**;

FIG. **7** is a longitudinal cross-sectional view of a bone with an alternative embodiment of an intramedullary bone fixation device partially inserted into the intramedullary canal;

FIG. **8** is a longitudinal cross-sectional view of a bone with the intramedullary bone fixation device of FIG. **7** implanted inside a second intramedullary bone fixation device;

FIG. **9**A is an enlarged cross-sectional view of one section of the bone and intramedullary bone fixation devices of FIG. **8**;

FIG. **9**B is an enlarged cross-sectional view of another section of the bone and intramedullary bone fixation devices of FIG. **8**;

FIG. **9**C is an enlarged cross-sectional view of another section of the bone and intramedullary bone fixation devices of FIG. **8**;

FIG. **10** is a perspective cutaway view of an alternative embodiment of an intramedullary bone fixation device comprising a cage, rods, sutures and a thermoplastic matrix;

FIGS. **11**A-**11**E are cross-sectional views of the intramedullary bone fixation device of FIG. **10**, illustrating radial expansion of the device from a contracted state in FIG. **11**A to a fully expanded state in FIG. **11**E.

FIGS. **12**A-**12**E are cross-sectional views of an alternative embodiment of an intramedullary bone fixation device, illustrating radial expansion of the device from a contracted state in FIG. **12**A to a fully expanded state in FIG. **12**E.

FIG. **13**A is a perspective view of a support structure in a contracted state according to one alternative embodiment of the invention;

FIG. **13**B is a perspective view of the support structure of FIG. **13**A in an expanded state;

FIG. **14**A is a perspective view of a cage in a contracted state;

FIG. **14**B is an end view of the cage of **14**A in a contracted state;

FIG. **14**C is a perspective view of a cage in an expanded state;

FIG. **14**D is an end view of the cage of **14**C in an expanded state;

FIG. **15** is a perspective view of a slotted support structure;

FIG. **16**A is a perspective view of a shaft portion of a mechanical expansion apparatus suitable for use with the device of FIG. **1**;

FIG. **16**B is a perspective view of the complete mechanical expansion apparatus of FIG. **16**A;

FIG. **17** is a longitudinal cross-sectional view of a bone with an intramedullary bone fixation device in a contracted state and a balloon expansion apparatus in the intramedullary canal of the bone, and a regulator apparatus;

FIG. **18** is a longitudinal cross-sectional view of a portion of the bone of FIG. **17**, with the intramedullary bone fixation device in a contracted state and a balloon expansion apparatus of FIG. **17**;

FIG. **19** is a longitudinal cross-sectional view of the bone, intramedullary bone fixation device and balloon expansion apparatus of FIG. **17**, with the balloon in an inflated state and the intramedullary bone fixation device in an expanded state;

FIG. **20**A is an enlarged cross-sectional view of one section of the bone and intramedullary bone fixation device of FIG. **19**;

FIG. **20**B is an enlarged cross-sectional view of another section of the bone and intramedullary bone fixation device of FIG. **19**;

FIG. **20**C is an enlarged cross-sectional view of another section of the bone and intramedullary bone fixation device of FIG. **19**;

FIG. **21** is a longitudinal cross-sectional view of the bone, intramedullary bone fixation device and balloon expansion apparatus of FIG. **17**, with the balloon in a deflated state and the and intramedullary bone fixation device in an expanded state, with the balloon expansion apparatus partially removed from the intramedullary bone fixation device;

FIG. **22**A is a perspective view of a telescoping bone fixation device in an extended state according to one alternative embodiment of the invention;

FIG. **22**B is a longitudinal cross-sectional view of a connection between two nesting components of the telescoping bone fixation device of FIG. **22**A;

FIG. **23** is a perspective view of a telescoping bone fixation device with mesh-like components and a thermoplastic matrix according to another alternative embodiment of the invention, in an extended state;

FIG. **24** is a perspective view of a helically threaded telescoping bone fixation device according to yet another alternative embodiment of the invention, in a partially extended state;

FIG. **25**A is a perspective view of one nesting component of the helically threaded telescoping bone fixation device of FIG. **24**;

FIG. **25**B is a perspective view of another nesting component of the helically threaded telescoping bone fixation device of FIG. **24**;

FIG. **26** is a perspective view of a composite intramedullary bone fixation device;

FIG. **27** is a cross-sectional view of the proximal end of the composite intramedullary bone fixation device of FIG. **26**;

FIG. **28**A is a side view of a handle;

FIG. **28**B is proximal end view of the handle of FIG. **28**A;

FIG. **29** is a lateral partial cross-sectional view of a fractured bone;

FIG. **30** is a lateral view of a guidewire being inserted into the intramedullary canal of the fractured bone of FIG. **29**;

FIG. **31** is a lateral view of the handle of FIG. **28**A guiding the composite intramedullary bone fixation device of FIG. **29** over the guidewire of FIG. **30** into the fractured bone;

FIG. **32** is a lateral view of the guidewire of FIG. **30** being removed from the intramedullary canal of the fractured bone;

FIG. **33** is a lateral perspective view of the handle of FIG. **28**A and a balloon expansion apparatus;

FIG. **34** is a lateral perspective view of a tube which comprises a portion of the balloon expansion apparatus of FIG. **33**;

FIG. **35** is a lateral perspective view of the balloon expansion apparatus of FIG. **33**;

FIG. **36** is an enlarged cross-sectional view of a connection assembly of the balloon expansion apparatus of FIG. **33**;

FIG. **37** is a lateral view of the composite intramedullary bone fixation device and the handle, connected to a set of hoses;

FIG. **38** is a lateral view of the composite intramedullary bone fixation device, handle, and hoses of FIG. **37**, connected to a cartridge and a pump, and showing the expansion of a portion of the bone fixation device;

FIG. **39** is a lateral view of the expanded composite intramedullary bone fixation device in the intramedullary canal of the fractured bone;

FIG. **40** is a perspective view of an implanted composite intramedullary bone fixation device connected to a heat source, an expansion apparatus and a pump;

FIG. **41** is a perspective view of a balloon expansion apparatus with a heating mechanism integrated into the balloon;

FIG. **42** is a perspective view of a balloon expansion apparatus with a heating mechanism integrated into a sleeve covering the balloon; and

FIG. **43** is a perspective view of an implanted composite intramedullary bone fixation device and expansion apparatus connected to an air heating and pressure control system.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. **1**, a perspective view illustrates an embodiment of an intramedullary bone fixation composite device **10**, where composite is defined as at least two non-identical materials deliberately combined to form a heterogeneous structure with desired or intended properties. The composite device **10** comprises a support structure **11** and a thermo-chemically activated thermoplastic matrix **16**. The support structure **11** comprises a cage **12**, and at least one stiffening rod **14**. The composite device **10** is generally tubular in form and has a longitudinal axis **24** and a transverse axis **26**. A hollow central core **18** extends the length of the device **10**, surrounded by the cage **12** and rods **14**, which are embedded in the thermoplastic matrix **16**. An outer perimeter **22** bounds the outer surface of the composite device **10**. The composite device **10** is an implant which is able to transition from a contracted and flexible state for introduction into the intramedullary canal, to an expanded and hardened state providing rigid support and alignment for fixation of the surrounding bone, once implanted and allowed to expand to the perimeter of the canal. The thermoplasticity of the matrix **16** allows the composite device **10** to conform to the shape of the surrounding intramedullary canal at a first state, and harden in its conformed shape at a second state providing torsional, axial, and bending reinforcement of the bone fragments during bone healing. When contracted for insertion (or removal), a diameter **20** along the transverse axis **26** of the device is reduced, and the length along the longitudinal axis **24** of the device may be constant or increased. When expanded within the intramedullary canal, the diameter **20** is increased, and the length may be constant or decreased.

As seen in FIG. **2**, the cage **12** is an elongated, generally web-like tube which allows radial expansion and contraction over at least part and preferably all of its length, and bending flexibility as bending loads are applied. The cage **12** has a first end **30**, a second end **32** and a sleeve **34** which extends between the ends. The sleeve **34** has an attachment portion **36** and a web-like stent portion **38**. The cage is hollow and generally circular in cross-sectional shape, although the web-like construction allows the cross-sectional shape to vary to conform to the contours of the surrounding intramedullary canal. The shape of the intramedullary canal varies along its length, and its cross-sectional shape may be substantially circular, generally triangular or another shape. The cage **12** may comprise a tubular woven or braided cage, a laser cut tubing cage, a machined cage, or a chemically etched tubing cage made from materials such as Nitinol, stainless steel, Co—Cr, Titanium alloys, Tantalum, plastic, polymer, ceramic or other biocompatible materials, among others. In the embodiment depicted, the stent portion **38** comprises a

majority of the sleeve **34**. However, in other embodiments the stent portion may be a smaller proportion of the sleeve, or comprise the entire sleeve. Attachment portions **36** may be located at one, both, or neither of the ends of the sleeve, or intermittently along the sleeve length.

Referring to FIG. **3**, possible configurations of the web-like structure of the stent portion **38** are shown, comprising examples of commercially available stent shapes. These figures show the approximate pattern of the web-like structure. These patterns are adaptable to a variety of lengths, diameters, density of repeatable patterns, wire thicknesses, web areas, and other structural characteristics such that the general stent shape can be configured to a particular bone morphology and size. FIG. **3**A is representative of a Johnson and Johnson Palmaz-Schatz™ Version 2 stent. FIG. **3**B represents a Medtronic Wiktor™ stent. FIG. **3**C represents the general shape of a Schneider "Magic" Wallstent™ stent. FIG. **3**D represents a Scimed NIR™ stent. FIG. **3**E represents an Arterial Vascular Engineering (AVE™) Microstent. FIG. **3**F is representative of a Biotronik Stent™. FIG. **3**G is meant to represent the general shape and construct of a Johnson and Johnson Palmaz-Schatz™ stent. FIG. **3**H represents a Global Therapeutics Freedom™ stent. FIG. **3**I is drawn to represent the adaptable structure of a Scimed Radius™ stent which like all the previously presented representative figures can be configured to the length, diameter and size needed to conform to the intramedullary shape of a particular bone. The stent portion may also be configured with more than one pattern along its length or diameter if needed to better conform to the desired geometry. The stent portion need not be a commercially available stent; it may also have a unique configuration which is constructed from wire, woven, machined, laser cut, or chemically etched.

FIG. **4** is an enlarged view of the first end **30**, the attachment portion **36** and part of the stent portion **38** of the cage **12**. The attachment portion **36** comprises struts **40** which extend from the stent portion **38** and terminate at loops **42**, which allow for the attachment of instruments for device placement, adjustment and removal. Other fasteners such as holes or hooks, among others, may be used instead of loops. Between the struts **40** at the first end **30**, linkages **44** connect each strut to the adjacent strut. The linkages allow for radial and longitudinal contraction and expansion of the struts **40** and therefore the first end **30**, as the device is contracted and expanded during implantation and removal. The web-like configuration of the stent portion **38** allows for radial and longitudinal contraction and expansion of the remainder of the cage **12**.

Referring to FIG. **5**, at least one, and optionally, a plurality, of stiffening rods **14** are oriented parallel to the longitudinal axis of the cage **12** and are contained by the cage in such a way as to allow the stiffening rod(s) to move radially with the cage as the cage contracts and expands. Each rod **14** has a first end **50**, a second end **52** and a shaft **56**. Each rod **14** may have loops, holes, hooks or other attachment structures at the second end **52** to connect to second end **32** of cage **12**. The rods **14** may be threaded loosely or otherwise linked into the stent portion **38** of the cage **12**. Holes (not shown) may extend transversely through the rods, and individual webs of the stent portion may pass through the holes to retain the rods. The rods **14** may extend the full length of the cage **12**, or preferably from the second end **32** of the cage to the upper end of the stent portion **38**. The stiffening rods **14** can be made from any biocompatible material such as stainless steel, cobalt chromium alloys, tantalum, zirconium alloys, titanium or titanium alloys, particularly beta titanium alloys. The stiffening rods **14** can also be made from non-metal biocompatible materials such as PEEK, Acetal, bioabsorbable materials, ceramics and biocomposites. Each stiffening rod **14** is sufficiently flexible to temporarily bend as the device (in a contracted state) is introduced into the intramedullary canal. Additionally, the rods may be knurled, threaded or otherwise treated to provide adhesion and interdigitation of the matrix and cage. Once the device **10** is inserted and expanded radially, the rods **14** are aligned parallel to the longitudinal axis of the bone and line the inner surface of the canal, within the cage and matrix of the device.

The ratio of longitudinal contraction to radial expansion of the composite device **10** varies depending upon the configuration of the stent portion of the cage, the length of the linkages, and the length and placement of the rods. Some embodiments have a low ratio, in which a small decrease in the length of the cage results in a large increase in the radial expansion (as measured by change in the core diameter **20**). Other embodiments have a 1:1 ratio (a contraction in cage length results in an equal measurement of radial expansion), or a higher ratio, in which a large decrease in longitudinal contraction produces a small increase in radial expansion. The choice of embodiment will depend upon factors such as the length and diameter of the particular bone to be fixed, accessibility to the bone, and severity of the fracture, among others.

Referring to FIG. **6**, the thermoplastic matrix **16** may be thermo-mechanically or thermo-chemically activated, and may surround the support structure **11** of FIG. **2**, or the support structure of any of the embodiments described below. The matrix **16** comprises a thermo-chemically activated material which has physical properties that change between a first and second state. For example, the material may be flexible and deformable at a first state and harder and more rigid at a second state. This can be accomplished by changing factors such as the molecular structure of chemical components of the matrix **16** from one state to another. For the purposes of this disclosure, thermo-chemically activated materials are materials which have physical properties which may change between a first state and second state by chemical, thermal, or other processes which change the molecular structure of a material, and thus the physical properties of the material. These processes may include, but are not limited to: changing the temperature of the material, exposing the material to gamma radiation and altering the crosslinking bonds between molecular chains in the material, exposing the material to ultraviolet radiation causing the material to cure and harden, exposing the material to a second material allowing cross-linking and molecular bonding, allowing the material to harden over time by increasing the crystallinity within the molecular structure, and other methods that alter the bonding between the molecules in the material and correspondingly alter its material properties. Within this disclosure, the term thermo-chemically activated may also be referred to as thermoplastic.

The matrix **16** may comprise a thermoplastic biocompatible polymer or polymer blend comprising polymers such as polylactic acid (PLA), poly ϵ-caprolactone (PCL), trimethylene carbonate (TMC), polyglycolic acid (PGA), poly l-lactic acid (PLLA), poly d-l-lactide (PDLLA), poly-D,L-lactic acid-polyethyleneglycol (PLA-PEG) or other biocompatible polymers. Each of these polymers has a glass transition temperature T_g such that when raised to a temperature above its T_g, the polymer is rubbery, flexible and substantially deformable. When lowered to a temperature below its T_g, the polymer is crystallized and substantially hardened. Each of these polymers or blends is capable of being transformed by the application of energy to a first thermo-chemical state, in which it is at a temperature above its glass transition tempera-

ture T_g. When, through dissipation of energy, the temperature is reduced to below T_g, the polymer or blend is at a second thermo-chemical state. These thermoplastic properties of the polymers allow them to be repetitively heated to above T_g, and subsequently cooled to below T_g, moving repeatedly between the first and second thermo-chemical states.

Preferred polymers have a glass transition temperature T_g that is above body temperature, but below the temperature known to cause thermal necrosis of tissues. A preferred blend is crystallized and substantially rigid at human body temperature, and has a T_g which ranges from about 10° C. above body temperature to about 35° C. above body temperature. This acceptable T_g range is between about 50° C. and about 80° C. and preferably between about 55° and about 65° C. Preferably, the thermoplastic matrix **16** comprises a blend of polymers such as PCL and PLA, or PCL and PGA. Table 1 displays the melting points (T_m), glass transition temperatures (T_g) and thermal decomposition temperatures (T_{dec}) of selected synthetic absorbable polymers.

TABLE 1

Melting, glass transition and thermal decomposition temperatures of selected synthetic absorbable polymers.

Polymer	T_m (° C.)	T_g (° C.)	T_{dec} (° C.)
PGA	230	36	260
PLLA	170	56	240
PLA	—	57	—
PCL	60	−62	—
Polyglactin910	200	40	250
Polydioxanone	106	<20	190
Polyglyconate	213	<20	260

Additional biocompatible polymers which may be included in the matrix **16**, individually or in a blend, comprise aliphatic polyesters including polyglycolide, poly(dl-lactide), poly(l-lactide), poly(δ-valerolactone), polyhydroxybutyrate; polyanhydrides including poly[bis(p-carboxyphenoxy) propane anhydride], poly(carboxy phenoxyacetic acid), poly(carboxy pheoxyvaleric acid); polyphosphazenes including aryloxyphosphazene polymer and amino acid esters; poly(ortho esters); poly(p-dioxane); poly(amino acids) including poly(glutamic acid-co-glutamate); erodable hydrogels; and natural polymers including collagen (protein) and chitosan (polysaccharide).

The thermoplastic matrix **16** may further include at least one bioactive material to promote growth of bone material and accelerate healing of fractures. These bioactive materials include but are not limited to hydroxylapatite, tetracalcium phosphate, β-tricalcium phosphate, fluorapatite, magnesium whitlockite, β-whitlockite, apatite/wollastonite glass ceramic, calcium phosphate particle reinforced polyethylene, bioactive glasses, bioactive glass ceramics, polycrystalline glass ceramics, and polyethylene hydroxylapatite.

The support structure **11** may be embedded in the thermoplastic matrix **16** through insert molding, pulltrusion, by dipping the support structure into the thermoplastic matrix material while it is at a temperature above T_g, or by other coating methods. A variety of different methods may alternatively be used to assemble the thermoplastic matrix **16** and the support structure **11**.

Referring to FIG. **7**, a longitudinal cross-section of a bone illustrates implantation of an intramedullary bone fixation composite device **710**. The method illustrated in FIG. **7** may also be used for implantation of composite device **10** and other devices according to alternative embodiments. Composite device **710** comprises a support structure **711** and a thermo-chemically activated thermoplastic matrix **716**. The support structure **711** comprises a stent-like cage **712** (not shown) and a plurality of rods **714** (not shown).

A percutaneous portal **60** is created into the intramedullary canal **2**, preferably in the proximal or distal metaphysical region of the bone. The opening may not be parallel to the longitudinal axis of the bone; it may be transverse or at an acute angle relative to the longitudinal axis of the bone. If necessary to open the canal space and prepare it for the implant, the canal is evacuated using a sequence of pulse lavage, brushing, and suction. A delivery tube **62** may be advanced into the percutaneous portal **60**. The composite device **710**, in a lengthened and contracted state, is heated immediately prior to implantation to a first thermo-chemical state, so that the thermoplastic matrix **716** is above its glass transition temperature and is therefore substantially deformable and rubbery enough to be flexed as it is introduced through the percutaneous portal and into the intramedullary canal. For the purposes of this disclosure, a structure is "substantially deformable" when it requires significantly less force to deform the structure than when it is "substantially hardened". In the preferred embodiment, a structure is substantially deformable when is requires less than half the force to deform it than would be required in the substantially hardened state.

Heating of the composite device **710** to reach the first thermo-chemical state may be accomplished by means including soaking the implant in a hot saline bath, application of ultrasonic vibratory energy, application of radiant heat energy, use of a local radiation emitter (including ultraviolet, visible light, and/or microwave energy), use of a laser energy emitter, use of inductive heat energy, electrical resistive heating of the cage or the delivery instrument, or heating of an expansion apparatus, among others.

The composite device **710** is inserted into the delivery tube **62**, pushed through the tube and advanced into the intramedullary canal **2** until the composite device **710** is contained within the confines of the canal. Optionally, the composite device **710** may be inserted directly through the percutaneous portal **60** without passing through a delivery tube **62**. A portion of the composite device **710** may be surrounded by a protective sheath **749**, which is positioned so that it covers the device **710** at the point of the bone fracture. The device **710** is then expanded radially. As the support structure **711** expands, the stiffening rods **714**, the cage **712** and thermoplastic matrix **716** move radially outward and are eventually aligned along the wall of the intramedullary canal, parallel to the longitudinal axis of the bone. The composite device **710** is allowed to cool to below the low glass transition temperature T_g, thus attaining the second thermo-chemical state, and the matrix **716** crystallizes. As the matrix crystallizes it becomes substantially hardened and conforms to the shape of the surrounding intramedullary canal, and the cage **712** and stiffening rods **714** are fixed in the thermoplastic matrix **716** along the wall of the canal. The shape of the intramedullary canal can vary along the length of the bone, with the canal being generally circular in the diaphysial region near the midpoint of the bone and irregular in the metaphysial regions near the ends of the bone. Although the thermoplastic matrix **716** is in a generally tubular shape as the composite device **710** is inserted, the thermoplastic qualities of the matrix allow it to conform to the shape of the intramedullary canal around it, and it crystallizes in that shape, thus providing torsional strength and support to the surrounding bone. The ability of the thermoplastic matrix **716** to conform to the irregularities in the intramedullary canal allows the device **710**, and the stabilized bone, to withstand greater torsional forces than

would a device with a constant circular shape which did not conform to the canal. For the purposed of this disclosure, "substantially hardened" means the thermoplastic matrix is crystallized and sufficiently hard that it will not change shape when exposed to manual pressure or mechanical pressures.

Deformation and/or radial expansion and of the composite device **710** to conform to the intramedullary canal can be accomplished in several ways. A deformation apparatus (such as those shown in FIGS. **16** and **17**) may be introduced into the central core of the composite device **710** before or after it has been inserted into the intramedullary canal. The deformation apparatus is expanded, and forces radial expansion of the composite device **710** until it fills the confines of the canal. The deformation apparatus may comprise a heat source to raise the temperature of the thermoplastic matrix **716**. Alternatively, the cage **712** may be constructed with an outward spring bias, introduced into the intramedullary canal and allowed to expand. In another embodiment which is described in detail below, a balloon apparatus (such as that shown in FIG. **17**) is introduced into the central core of the composite device **710**. As the balloon is inflated with heated gas or liquid, it expands, and consequently induces expansion of the composite device **710**. Once the device is expanded, the balloon can be deflated and removed. It is appreciated that these deformation and expansion techniques and apparatuses may also be employed with composite device **10** and other embodiments of intramedullary bone fixation devices disclosed herein.

Referring to FIG. **8**, a longitudinal cross-section shows two composite devices **710**, **750** implanted in a bone. Deploying two bone fixation devices nested in this manner may provide additional strength, rigidity and resistance to torsion than would be available from one bone fixation device. Twice the thermoplastic matrix material and twice the support structure are present to provide additional stabilization.

Composite device **750** comprises a thermoplastic matrix **756**, which surrounds a support structure which includes a cage **752** and a plurality of rods **754**. The configuration of matrix **756**, cage **752** and rods **754** may be identical to that of composite device **710**. Prior to implantation, the composite device **750** is partially radially expanded. The composite device **710** is contracted, and slid into a hollow central core **758** of the composite device **750**. Together, the two devices **710**, **750** are heated until the thermoplastic matrices **716**, **756** reach the first thermo-chemical state. The two devices **710**, **750** are introduced as a unit into the intramedullary canal. The inner disposed composite device **710** is expanded using one of the techniques previously described. As the inner composite device **710** expands, it pushes radially against the outer disposed composite device **750**, forcing it to expand radially until it contacts and conforms to the wall of the surrounding intramedullary canal.

Alternatively, composite devices **710**, **750** may be introduced individually into the intramedullary canal. Composite device **750** may be introduced first, heated and expanded. Composite device **710** is then introduced into the hollow central core **758** of composite device **750** after is it in the intramedullary canal. After both devices **710**, **750** are in the canal, composite device **710** is heated and expanded, pushing radially against the outer composite device **750**.

The thermoplastic matrix **716** surrounding the composite device **710** may contact and conform to the thermoplastic matrix **758** of the composite device **750**. The two devices **710**, **750** are allowed to cool to the second thermo-chemical state and harden.

Referring to FIGS. **9**A-**9**C, three cross-sectional views along different parts of the bone depicted in FIG. **8** are shown, with devices **710**, **750** implanted in the intramedullary canal. In FIG. **9**A, the intramedullary canal **2** is relatively wide and circular in shape, resulting in a wide, circular central hollow core **718**. Also, the thermoplastic matrices **716**, **756** are relatively thin, and the rods **714**, **754** are spaced relatively far apart, as the devices **710**, **750** had to expand radially farther to contact the wall of the intramedullary canal at that point. As seen in FIG. **9**B, at this point along the bone the intramedullary canal is smaller in diameter and more irregular in shape. The thermoplasticity of the matrices **716**, **756** allows the devices **710**, **750** to match the size and shape of the canal. As seen in FIG. **9**C, at this point along the bone the intramedullary canal is narrow in cross-section and substantially triangular in shape. According, the thermoplastic matrices **716**, **756** are thicker and the rods **714**, **754** are closer together, since the devices **710**, **750** are relatively less expanded.

Referring to FIG. **10**, an alternative embodiment of an intramedullary bone fixation composite device is shown in a cutaway view. Composite device **810** comprises support structure **811** and a thermo-chemically activated thermoplastic matrix **816**. Support structure **811** comprises a cage **812**, a plurality of rods **814**, and a plurality of sutures **815** which connect the cage to the rods. The thermo-chemically activated matrix **816** surrounds the cage **812**, rods **814** and sutures **815** such that they are embedded in the matrix. The sutures **815** are interwoven around and between the cage **812** and the rods **814** to connect the cage **812** to the rods **814** in a manner that allows regulated movement of the cage **812** and the rods **814** relative to one another.

Alternately, the sutures may be knit into a sleeve that holds the array of rods and surrounds the cage. The interweaving may be constructed in such a way as to allow radial expansion of the cage **812** and the rods **814** from a contracted position in which the cage **812** is lengthened and the rods **814** are tightly packed together, to an expanded position in which the cage **812** is shortened, radially expanded and the rods **814** are arrayed around the cage with relatively more space between each rod. The cage **812** may comprise web-like stent material similar to stents depicted in FIGS. **3**A-**3**I, or may comprise another woven or laser cut stent-like material. The rods **814** may be similar to the rods **14** depicted in FIG. **5**. The thermo-chemically activated thermoplastic matrix **816** may be similar to the thermo-chemically activated thermoplastic matrix **16** described previously and depicted in FIG. **6**. The sutures may comprise any of several commercially available sutures, including Dyneema Purity® Ultra High Molecular Weight Polyethylene (UHMWPE), or bioabsorbable multifilament polylactic acid (PLA) sutures such as PANACRL™, among others.

Composite device **810** may be introduced into the intramedullary canal in the same manner as previously described for composite device **710**. Energy is applied to composite device **810**, heating it until the thermo-chemically activated matrix **816** reaches the first thermo-chemical state, and is flexible and rubbery. The composite device **810** is contracted so that it is sufficiently flexible to be inserted into the intramedullary canal through an opening in the bone, an opening which may not be parallel to the intramedullary canal. The composite device **810** is inserted into the canal and expanded by one of the expansion methods previously described. When the device is expanded within the intramedullary canal, the thermo-chemically activated matrix **816** contacts and is conformed to the walls of the intramedullary canal. The device **810** is allowed to cool and the thermo-chemically activated matrix **816** attains the second thermo-

chemical state, and hardens sufficiently to fix the support structure **811** in its expanded position within the intramedullary canal.

Referring to FIGS. **11**A-**11**E, a series of five cross-sectional views illustrate the expansion of composite device **810** from a contracted position to a fully expanded position. Beginning with FIG. **11**A, a hollow central core **818** of composite device **810** is substantially circular. As composite device **810** expands, the cage **812** and the hollow central core **818** increase in diameter and the thermoplastic matrix **816** stretches to fit around the cage **812**. At the most expanded state illustrated in FIG. **11**E, the thermoplastic matrix **816** is substantially thinner than at the most contracted state. In FIG. **11**A, the array of rods **814** are relatively closely packed near one another; in FIG. **11**E they are spread apart and are substantially equidistantly arrayed about the hollow central core **818**.

FIGS. **12**A-**12**E illustrate an alternative embodiment of a composite device in five cross-sectional views. Similar to composite device **810**, composite device **910** comprises a support structure **911** with a cage **912**, a plurality of rods **914**, and a plurality of sutures **915** which connect the cage to the rods. A thermo-chemically activated thermoplastic matrix **916** surrounds the cage **912**, rods **914** and sutures **915** such that they are embedded in the matrix. As most clearly seen in FIG. **12**C, in this embodiment, the thermoplastic matrix **916** is configured in a series of folds **917**, as compared to the circular configuration seen for thermoplastic matrix **816** in FIG. **11**C. The folded configuration of the thermoplastic matrix **916** results in a star-shaped hollow central core **918**. The star-shaped hollow central core **918** is smaller in terms of cross-sectional open space, as much of the space is taken up by the folds of the thermoplastic matrix **916**. Therefore, the thermoplastic matrix **916** is thicker in this embodiment than in other embodiments such as device **810**. Thus, as seen in FIG. **12**E, the fully expanded composite device **910** has a thicker thermoplastic matrix, which may result in additional support for the surrounding bone during the healing process.

Composite device **910** may be introduced into the intramedullary canal in the same manner as previously described for composite devices **710** and **810**. Energy is applied to composite device **910**, heating it until the thermo-chemically activated matrix **916** reaches the first thermo-chemical state, and is substantially deformable, flexible and rubbery. The composite device **910** is contracted into the deeply folded position seen in FIG. **12**A, so that it is sufficiently flexible to be inserted into the intramedullary canal through an opening in the bone. The composite device **910** is inserted into the canal and radially expanded by one of the expansion methods previously described. A specifically configured implant expander such as a star-shaped balloon expansion device (not shown) may be used to expand the device **910**. When the device is radially expanded within the intramedullary canal, the thermo-chemically activated matrix **916** contacts and is conformed to the walls of the intramedullary canal. The device **910** is allowed to cool and the thermo-chemically activated matrix **916** attains the second thermo-chemical state, and substantially hardened, fixing the cage **912** and rods **914** in their expanded positions within the intramedullary canal. In the case of a larger bone, two composite devices **910** may be deployed, one inside the other, to provide additional support to the bone.

Referring to FIGS. **13**A and **13**B, one alternative embodiment of a support structure **71** suitable for use in an intramedullary bone fixation device has an hourglass shape. In the context of the present invention, an hourglass shape is a generally longitudinal, columnar shape in which the two end portions of the column are wider in diameter than a middle portion of the column. The support structure **71** comprises a cage **72** and rods **14**. In this embodiment, the diameters of cage ends **74**, **76** are greater than the diameter of a cage sleeve **78**. In order to clearly view the configuration of cage and rods, a thermoplastic matrix is not shown. A matrix similar to that of the thermoplastic matrix **16** of FIG. **1** may be used in conjunction with support structure **71**, or it may have a different configuration. The hourglass shape enables the tubular support structure **71** to conform to the contours of the intramedullary canal of a long bone, in which the metaphysical regions at the ends of the bone are irregular and may be greater in diameter than the diaphysial region near the midpoint of the bone. In the embodiment depicted, the hourglass shape is achieved by the particular threading of the rods within the stent portion of the cage. At the first **74** and second **76** ends, the rods **14** are contained within the confines of the cage **72**; toward the center of the sleeve **78**, the cage is contained within the circle of the rods **14**. In FIG. **13**A, the support structure **71** is shown in the contracted state (for insertion or removal); in FIG. **13**B, the expanded state is shown. The support structure **71** may be inserted in the same manner as described previous for support structure **11**, and the same expansion methods described previously may be used to expand the support structure **71**.

One alternative embodiment of an intramedullary bone fixation device (not shown) comprises a laser-cut cage which is constructed with an outward spring bias. In this embodiment, the device is compressed prior to implantation by holding the rods steady and pulling longitudinally on the cage. The web-like configuration of the cage permits the cage to lengthen while simultaneously its core diameter contracts, enabling the device to be narrow and flexible enough for insertion. The device is introduced into the intramedullary canal and the cage is released. Upon release, the outward spring bias of the cage causes the cage to expand radially and simultaneously shorten. Radial expansion continues until the outer perimeter of the device contacts the inner wall of the intramedullary canal. The web-like configuration of the cage also allows it to conform to variations in the geometry of the intramedullary canal. This embodiment may also include the thermoplastic matrix, wherein prior to the compression step described above, the thermoplastic matrix is heated to the substantially deformable first thermo-chemical state, so it is flexible as the device is compressed, inserted and expanded. After insertion and radial expansion, the energy is allowed to dissipate and the thermoplastic matrix attains the substantially hardened second thermo-chemical state.

Referring to FIGS. **14**A through **14**D, another alternative embodiment of the invention comprises a cage with an outward spring bias, which may be used in conjunction with a thermoplastic matrix such as that depicted in FIGS. **1** and **6**. FIG. **14**A is a perspective view of a cage **112**, cut with a plurality of accordion-type folds **114** which unfold as the cage expands radially. Alternating with the folds **114** are longitudinal ribs **116**, and a hollow central core **115** extends the length of the cage **112**. Each rib **116** has a longitudinal channel **118** which may hold a stiffening rod. The cage may be laser-cut or machined from metal, or may comprise a plastic material or a thermo-chemically activated thermoplastic matrix material, as described above. The cage **112** may have a straight shape with a constant diameter, or may have an hourglass shape in which the two ends are wider than the central section. Other shapes may alternatively be used for different bone morphologies.

FIG. **14**B is an end view of the cage **112** in a compressed state, showing the tight compaction of the folds **114** and ribs

116. FIG. 14C is a perspective view of the cage 112 after radial expansion, and FIG. 14D is an end view of the expanded cage 112. In this embodiment, the support structure can be compressed for implantation by a binding material which is wrapped or tied around the compressed cage. After insertion into the intramedullary canal, the cage is released by cutting or removal of the binding material. Once released, the outward spring bias of the cage 112 causes the cage 112 to expand radially in the same manner as described for the previous embodiment.

In another embodiment the support structure may be monolithic; that is, formed as a single unit. The cage and rods are formed together, such as by a machining process and remain connected together. Referring to FIG. 15, an embodiment of a monolithic support structure 111 is shown in an expanded state. This embodiment has no channels for rods, but consequently has ribs 117 between the accordion folds 114 which are solid and comprise more material, thus providing rigidity similar to the rods of other embodiments. Between the ribs 117, the accordion folds 114 have a plurality of slots 119. The slots 119 allow for less material and thus more flexibility of the support structure when compressed. Additionally, when compressed, the tight packing of the ribs 117 between the accordion folds 114 allows the support structure 111 to flex sufficiently for insertion into the intramedullary canal. The monolithic support structure 111 may be used in conjunction with a thermoplastic matrix. Contraction, insertion and expansion of the monolithic support structure 111 may be in the same manner as described previously for the cage 112.

In another embodiment of the invention, at least two support structures and/or cages such as those depicted in FIGS. 14 and 15 can be nested, one within the other. A first support structure 111 or cage 112 embedded in the thermoplastic matrix 16 is heated to the first thermo-chemical state, compressed, inserted into the intramedullary canal, and expanded. A second support structure 111 or cage 112 embedded in the thermoplastic matrix 16 is similarly compressed and inserted into the central core 115 of the first support structure. When the second structure 111 or cage 112 expands, it pushes radially against the first structure 111 or cage 112. As described previously for other embodiments, the thermoplastic matrix 16 surrounding the first support structure conforms to the contours of the intramedullary canal. Within the first support structure, the thermoplastic matrix 16 surrounding the second support structure conforms to the surrounding first support structure. The matrix material surrounding both the first and second structures cools to the second thermo-chemical state and crystallizes. This double layer of matrix material and support structures provides enhanced support and rigidity to the surrounding bone.

The cage 112 and support structure 111 embodiments depicted in FIGS. 14 and 15 can alternatively be constructed without an outward spring bias. The compressed cage 112 or support structure 111 may be surrounded by the thermoplastic matrix 16. As described previously, the device is heated so the thermo-plastic matrix 16 reaches the first thermo-chemical state and the device is flexed and inserted into the intramedullary canal. In this case, an expansion apparatus or balloon mechanism as previously described, or other expansion mechanism is inserted into the central core 115 and used to expand the device after it is implanted. Once the device is expanded, energy dissipates into the surrounding tissue, the matrix attains the second thermo-chemical state, and the cage 112 or support structure 111 is fixed within the cooled, crystallized matrix 16. The expansion apparatus, balloon mechanism, or other expansion mechanism may then be removed from the central core 115.

One alternative embodiment of an intramedullary bone fixation composite device (not shown) comprises a thermoplastic matrix which is not continuous along the entire length of the corresponding cage or support structure. In this embodiment, the matrix comprises at least two separate tube-like portions, each of which surrounds one end of the cage or support structure and extends partway along the sleeve. This discontinuous configuration of the matrix contributes to an hourglass shape and allows less matrix material to be used. This matrix configuration can be used with either a cage with an outward spring bias, or with a cage with no outward spring bias.

Another alternative embodiment of an intramedullary bone fixation composite device (not shown) comprises a support structure which comprises at least one rod, and no cage. Prior to implantation, the matrix is heated to the first thermo-chemical state and formed into a tubular shape around the rods, which are subsequently embedded in the matrix. The device is flexed and inserted into the patient. While the matrix is still in the first thermo-chemical state, an expansion apparatus or balloon is inserted into the center of the tubular device and used to expand the device within the intramedullary canal. As the device expands, the rods and the matrix material are pushed radially to the inner wall of the intramedullary canal. After expansion, the device is allowed to cool to the second thermo-chemical state, and the matrix hardens, fixing the rods in their positions around the inner wall of the canal.

Another alternative embodiment of an intramedullary bone fixation device (not shown) comprises a support structure which comprises a cage manufactured of the thermoplastic matrix material, and rods. During manufacture the matrix material is heated above its T_g and extruded into a cage-like form. During or after extrusion the rods are interwoven, braided in, or otherwise attached as described previously. To implant the device, the device is heated above the T_g of the matrix to attain the first thermo-chemical state, contracted, flexed, inserted and expanded as described previously.

FIGS. 16A and 16B illustrate an implant expansion device which may be used to deform and expand several of the intramedullary bone fixation devices described previously, such as composite device 10, composite devices 710, 750 and 810, a device incorporating support structure 71, or other devices which incorporate a cage or support structure without an outward spring bias. A mechanical expansion apparatus 500 is longitudinally insertable into the central core of the intramedullary bone fixation device. As seen in FIG. 16A, the mechanical expansion apparatus 500 has a shaft 514, which extends from a first end 510 to a second end 512. An adjustment nut 516 is threaded onto a threaded portion 515 of the shaft 514, adjacent the first end 510. A cone-shaped first expander guide 518 is also threaded onto the threaded portion 515 of the shaft 514, on the opposite side of the adjustment nut 516 from the first end 510. The second end 512 of the shaft 514 terminates in a cone-shaped second expander guide 519. The shaft 514 comprises a metallic material, and is sufficiently thin and flexible to be inserted into the central core of an intramedullary bone fixation while the device is in the intramedullary canal of a bone in a patient.

Referring to FIG. 16B, strung on the central shaft 514 and listed in their order of occurrence from the first expander guide 518 to the second expander guide 519 are: a first expander segment 520, a plurality of core segments 522, a central segment 524, another plurality of core segments 522, and a second expander segment 526. The core segments 522

and the central segment **524** comprise a relatively rigid material, while the expander segments **520**, **526** comprise a relatively rubbery, flexible material. The first expander segment **520** surrounds a portion of the first expander guide **518** in a sleeve-like manner, and the second expander segment **526** similarly surrounds a portion of the second expander guide **519** in a sleeve-like manner. The core segments **522**, central segment **524**, and expander segments **520**, **526** are initially placed loosely on the shaft **514** with space between each segment, so that the apparatus can flex while being inserted into the central core of the intramedullary bone fixation device.

After the intramedullary bone fixation device with a thermoplastic matrix (not shown) is placed in the intramedullary canal, the mechanical expansion apparatus **500** may be inserted through the delivery tube **62** (not shown) into the central core of the intramedullary bone fixation device. Then the adjustment nut **516** is turned, forcing the first expander guide **518** to advance along the shaft **514** toward the second expander guide **519** at the second end **512**. The first expander segment **520**, core segments **522**, central segment **524**, and second expander segment **526** are compressed together as they are held between the first and second expander guides **518**, **519**. The rubbery, flexible expander segments **520**, **526** expand radially as they are forced farther onto the cone-shaped expander guides **518**, **519**. As the expander segments **520**, **526** expand radially, they push the ends of the surrounding intramedullary bone fixation device outward radially, thus matching the generally hourglass shape of the intramedullary canal. Expansion is ceased when the outer perimeter of the intramedullary bone fixation device contacts the inner walls of the intramedullary canal. The expansion apparatus **500** may be kept in the central core of the intramedullary bone fixation device until the thermoplastic matrix cools to the second thermo-chemical state. The expansion apparatus **500** is contracted by turning the adjustment nut **516** in the opposite direction, and the apparatus **500** is then removed from the central core.

The expansion apparatus **500** may optionally include a heating element. In this configuration, it can heat the thermoplastic matrix of an intramedullary bone fixation device while in a patient, in order to adjust the conformity of the matrix within the intramedullary canal.

Referring to FIGS. **17-21**, an alternative method to deform and expand an intramedullary bone fixation device comprises an implant deformer which is a balloon expansion apparatus. As seen in FIG. **17**, a balloon expansion apparatus **600** configured to fit within a composite device **10** in the intramedullary canal of a bone comprises an elastic bladder **602** with an opening **604**. A set of flexible hoses comprising an input hose **606** and an output hose **608** are configured to extend from a regulator apparatus **610**, through the opening **604** and into the elastic bladder **602**. The regulator apparatus **610** is external to the patient, and comprises a pump to regulate flow, and a temperature regulator to regulate the temperature, of liquid which can flow into and out of the elastic bladder **602**. FIG. **17** depicts the hoses adjacent and parallel to one another; however they may be configured in alternative arrangements, including a concentric arrangement in which one hose surrounds the other. The hoses **606**, **608** terminate at differing positions within the bladder **602**.

Referring to FIG. **18**, a composite device **710** with a balloon expansion apparatus **600** already inserted into the central core **718** is introduced into the intramedullary canal of a bone. Introduction into the bone can be through the method described previously, in which the composite device (with the balloon apparatus in the central core) is heated so that the matrix attains the first thermo-chemical state. The composite device **710** plus balloon apparatus **600** are flexed and introduced into the intramedullary canal through the percutaneous portal **60**. A delivery tube **62** (not shown) may optionally be used during the introduction and expansion procedures. The input **606** and output **608** hoses are inserted through the balloon opening **604** ideally before the composite device **710** plus balloon apparatus **600** are introduced into the intramedullary canal, but can optionally be inserted into the balloon opening **604** after introduction into the intramedullary canal. A protective sheath **49** may surround the composite device **710** at the location of the bone fracture.

Referring to FIG. **19**, after the composite device **10** plus balloon apparatus **600** are within the intramedullary canal, inflation of the bladder **602** may begin. The external regulator apparatus **610** (not shown) pumps heated liquid such as water or saline solution, among others, through the input hose **606** into the elastic bladder **602**. The heat of the liquid maintains the thermoplastic matrix **716** of the composite device **710** at the deformable first thermo-chemical state. As the heated liquid fills the bladder **602**, the bladder expands. Contained within the composite device **710**, the bladder **602** eventually pushes outward, inducing radial expansion of the composite device **710**. As described previously, cage and rod components of the support structure **711** are connected in a web-like construction which allows them to expand radially. The thermoplastic matrix **716** surrounding the support structure **711** is at the heated first thermo-chemical state and is pushed radially by the expanding support structure, conforming to the surrounding intramedullary canal walls. The flexible, rubbery character of the matrix allows it to fit into the natural morphological variations in the wall of the intramedullary canal. A mesh-like end cap **746** on a second end **732** of the composite device **710** prevents the elastic bladder **602** from escaping or ballooning out of the second end **732**. The output hose **608**, which terminates at a location different from that of the input hose **606**, allows liquid to flow out of the balloon apparatus **600**. The regulator apparatus **610** maintains the flow, temperature and pressure of the liquid.

FIGS. **20A-20C** display cross-sections of the bone and the composite device **710** at three different locations along the length of the bone shown in FIG. **19**. At cross-section A-A in FIG. **20A**, the cross-sectional shape of the intramedullary canal is relatively circular. The device **710** has expanded to the wall of the canal, the matrix **716** is relatively thin, and the rods **714** are spaced relatively far apart. At cross-section B-B in FIG. **20B**, the canal is smaller and more rectangular in shape than at cross-section A-A. However, the deformable nature of the matrix **716** allows the matrix and the entire composite device **710** to expand differentially and conform to this variation in shape of the intramedullary canal. At cross-section C-C in FIG. **20C**, the cross-sectional shape of the intramedullary canal is relatively smaller, and has a triangle-like shape. Again, the matrix **716** and the composite device **710** can conform to this irregular shape. The rods **714** are relatively closer together and the matrix **716** is relatively thicker. The ability of the composite device **710** to closely conform to the confines of the intramedullary canal allows the device to withstand greater torsional forces than would a device with a constant circular shape which did not conform to the canal.

Referring to FIG. **21**, the balloon expansion apparatus **600** is depicted being withdrawn from the composite device **710**. After expansion of the elastic bladder **602** is accomplished as described previously, the liquid in the elastic bladder **602** may be cooled by pumping cool liquid in through input hose **606** and withdrawing warmer liquid through output hose **608** until

a consistently cooler liquid is in the bladder **602**. The cooler liquid in the bladder absorbs thermal energy from the matrix **716**, allowing it to cool and transform from the flexible first thermo-chemical state to the hardened second thermo-chemical state. Once the composite device **710** has thus cooled and hardened, the remaining liquid may be pumped out of the elastic bladder **602**, and the balloon expansion device **600** is pulled out of composite device **710** through the percutaneous portal **60**.

A protective, tubular insertion sheath (not pictured) may surround all or a portion of any of the above-described intramedullary bone fixation devices during the implantation procedure, and may optionally be removed following implantation. The insertion sheath may be very thin, and may prevent portions of the support structure or matrix from snagging on or scratching the intramedullary canal, or portions of the fractured bone. Once the device is inserted, the sheath may be removed by being pulling the sheath out through the delivery tube, while leaving the device behind.

With any embodiment of the device, after insertion of the device but before conclusion of the implantation procedure, x-ray, fluoroscopy, or other radiographic methods may be implemented to assess the alignment of the device relative to the bone. If alignment is unsatisfactory, a heating element (not shown) or a heatable expansion device such as the balloon apparatus **600** or mechanical expansion apparatus **500** as described previously may be introduced into the central core. The device is heated so the thermoplastic matrix again reaches first thermo-chemical state, and the device may then be removed and reinserted or otherwise adjusted until a satisfactory alignment is achieved. The device is allowed to cool, so the thermoplastic matrix returns to the second thermo-chemical state through the natural dissipation of energy into the surrounding tissue.

Post-implantation, the device may be removed if desired. The method of removal will vary, depending on the state of the decomposition of the biocompatible thermoplastic matrix. If the thermoplastic matrix is still intact, a percutaneous portal may be opened and a tube may be inserted. The tube may be the same as or similar to the delivery tube **62** described previously. A heating element or heatable expansion apparatus such as the mechanical expansion apparatus **500** or balloon expansion apparatus **600** is introduced into the central core, and the device is heated until the matrix reaches the first thermo-chemical state, above the glass transition temperature. The heat source is removed; the device may be contracted by holding the rods steady and pulling longitudinally on the cage. The device may be removed through the delivery tube, or directly through the percutaneous portal. If the thermoplastic matrix has been sufficiently absorbed so that it is no longer intact, no heating is required; the device is contracted and removed.

Another embodiment of the invention (not shown) comprises a support structure and an alternative form of the thermoplastic matrix, comprising an injectable form of a synthetic biodegradable polymer, poly-D,L-lactic acid-polyethyleneglycol (PLA-PEG). This biodegradable composite is temperature-sensitive so that when it is heated it takes on a liquid, semi-solid form and following injection, cools and becomes semi-solid. A structure such as support structure **11**, **711**, **811** or **71** is introduced into the intramedullary canal. The structure may have a protective sheath surrounding the portion of the structure which will be adjacent to the fracture location. Following insertion of the support structure into the intramedullary canal, and radial expansion of the support structure, heated PLA-PEG is injected through a flexible tube or catheter which is inserted through the delivery tube **62** into the central core. The liquid PLA-PEG flows through the web-like support structure, filling the canal and surrounding the support structure. The protective sheath prevents the PLA-PEG from contacting the fractured area of the bone. The PLA-PEG is allowed to cool and harden, and provides rigid support around the structure.

Referring to FIG. **22**A, a perspective view shows another embodiment of the invention, comprising a telescoping intramedullary fixation device **210**. This device comprises a central wire **212** surrounded by a series of five tubular nesting components **213-217**. Each tubular nesting component is substantially the length of the entire device **210** when all components are nested together, and each successive nesting component is slightly wider in diameter than the component it surrounds. Other embodiments of the telescoping intramedullary fixation device **210** may have fewer, or more, than five nesting components. The central wire **212** may have a solid core and may not be tubular, but is slender and thus sufficiently flexible to be inserted into the intramedullary canal. The nesting components **213-217** may comprise metal, a biocompatible polymer material, or a mesh-like stent material (such as those depicted in FIG. **3**), and may be embedded in a thermoplastic matrix material. FIG. **22**A displays the telescoping device **210** in a fully extended or telescoped position; however when completely implanted in a patient the device **210** is in a collapsed position in which the nesting components are concentrically nested together.

The first nesting component **213** surrounding the central wire **212** is slightly wider in diameter than the central wire **212**. Each successive nesting component **214-217** is slightly wider than the preceding one, and as the nesting components increase in diameter, the width of the wall of the component may decrease so that each nesting component is still flexible enough to be inserted into the canal. The wall thickness of each of the nesting components **213-217** may advantageously be selected such that the nesting components **213-217** are all nearly equally flexible. According to one alternative embodiment (not shown), the nesting components do not have solid walls but have slots in the walls to increase flexibility.

In a patient, the central wire **212** may first be inserted into the intramedullary canal. Then, successive nesting components **213-217** with increasing diameters are introduced into the intramedullary canal. The nesting component **213** with the smallest diameter is slid in around the central wire **212**; the nesting component **214** with the next largest diameter is slid in surrounding the first nesting component **213**, and the remaining nesting components **215-217** are inserted in a similar fashion. The largest nesting component **217** fits just inside the walls of the canal. After the components are inserted and collapsed together, an injectable, hardenable polymer such as bone cement or a biocompatible polymer such as PLA-PEG may be introduced into the canal to fill any spaces between the largest nesting component **217** and the wall of the canal. The largest nesting component **217** may have a sheath **219** which prevents the polymer from accessing the fractured area of the bone, as described previously. The nested set of nesting components **213-217** has a combined strength and rigidity which exceeds that of any of the individual nesting components, and the device **210** provides strength and support during bone healing.

FIG. **22**B is an enlarged, stylized cross-sectional view of the connection between nesting components **216** and **217**; however the figure is representative of the connections between each of the nesting components **213-217**. Nesting component **217** has a first end **230** with an inward-projecting first lip **234**. The next smallest nesting component **216** has a second end **232** with an outward-projecting second lip **236**.

The projecting lips **234**, **236** allow for easy removal of the apparatus. During removal, initially a slap hammer is used to break the largest nesting component **217** away from the bone cement. Nesting component **217** is pulled out first, and its inwardly-projecting lip **234** hooks the outwardly-projecting lip **236** of the next largest nesting component **216**, and causes it to be pulled out next, followed by the next largest nesting component **215**, until all the nesting components **213-217** are pulled out. The central wire **212** is removed separately after all the nesting components are removed.

Referring to FIG. **23**, another embodiment of a telescoping fixation device is shown in an extended state. In this embodiment, telescoping fixation device **310** comprises a series of nesting components **313-317**, each of which comprises a mesh-like stent portion embedded in thermo-plastic matrix material **318** similar to that of the thermoplastic matrix **16** of FIGS. **1** and **6**. Each nesting component **313-317** is substantially the length of the entire device **310** when all components are nested together. Prior to implantation, the device **310** is heated as described previously so that the thermoplastic matrix material **318** reaches the first thermo-chemical state, and is rubbery and flexible. The device **310** is telescoped out into an extended configuration, and introduced into the intramedullary canal through an opening transverse to the longitudinal axis of the bone. The central wire **312** is introduced first, and the adjacent and smallest nested component **313** is inserted so it nests around the central wire. The next smallest nested component **314** is nested about the smallest nested component **313**, and so on until all the remaining nested components **315-317** are introduced into the intramedullary canal and nested together. The device **310** is allowed to cool so that energy dissipates into the surrounding tissue, and the thermoplastic matrix material **318** of each nesting component **313-317** reaches the second thermo-chemical state, and hardens.

Referring to FIG. **24**, another alternate embodiment of a telescoping fixation device is shown, in a partially extended state. In this embodiment, telescoping fixation device **410** comprises a series of nesting components **413-417**, which are helically threaded so that during implantation each nesting component is threaded onto the preceding smaller component. The direction of the threading on each nesting component may alternate, so that each nesting component is threaded onto the next nesting component in the opposite direction from the previous one. Each nesting component **413-417** is substantially the length of the entire device **410** when all components are nested together. As with devices **210** and **310**, five nesting components are described, however in alternate embodiments the number and size of the nesting components may vary.

Similar to the telescoping fixation devices **210** and **310**, device **410** has a central wire **412** which is initially inserted into the intramedullary canal through a delivery tube **62** or similar interface. The first nesting component **413** is slid in around the central wire. The first nesting component **413** is tubular in form has a clockwise helical protrusion **420** which protrudes on the outside of the tube, winding in a clockwise direction along the length of the nesting component **413**.

Referring to FIGS. **25**A-**25**B, two adjacent helically threaded nesting components have threading configurations which wind in opposite directions. As seen in FIG. **25**A, the second nesting component **414** has a clockwise helical slot **422** which winds clockwise along its length, and a counter-clockwise helical protrusion **421** which winds counter-clockwise along its length. As nesting component **414** is inserted into the intramedullary canal, it is twisted clockwise so that its clockwise helical slot **422** fits over the clockwise helical protrusion **420** on the first nesting component **413**. As seen in FIG. **25**B, the third nesting component **415** has a counter-clockwise helical slot **423**, and a clockwise helical protrusion **420**. It is inserted and threaded onto the second nesting component **414** in a counter-clockwise fashion, so that its counter-clockwise helical slot **423** engages with the counter-clockwise helical protrusion **421** on the second nesting component **414**. Each remaining nesting component is threaded clockwise or counter-clockwise to engage with the smaller component nested inside of it. The outermost nesting component **417** may or may not have a helical protrusion.

The helical threading system varies in direction so that the entire device will not be loosened when the outermost component **417** is turned in one direction. In addition, this bi-directional threading system adds overall torsional strength to the telescoping fixation device **410**, since a twisting force in one direction will not disengage all the threading on the nesting components.

The telescoping fixation device **410** may be used in conjunction with an injectable hardenable polymer, such as bone cement or a biocompatible polymer such as PLA-PEG, among others. The fixation device **410** may be implanted as described previously, and the injectable polymer may then be injected into the intramedullary canal around the periphery of the device, to fix the device in place. The outermost nesting component **417** may have a protective sheath **419** which prevents the polymer from accessing the fractured area of the bone, as described previously. Removal of the device **410** is accomplished by breaking the device away from the polymer as described previously, then unthreading and removing each component **413-417** in a clockwise or counter-clockwise direction, beginning with the outermost component **417** and proceeding inward.

Another alternative embodiment of an intramedullary bone fixation device is depicted in FIG. **26**. Fixation device **1010**, which may also be described as an intramedullary nail, has an elongated shape and comprises a distally located nose portion **1012**, a central portion **1014** occupying a middle position, and a proximally located attachment portion **1016**. A bore **1017** extends the length of the device. The fixation device **1010** is designed to be inserted into the intramedullary canal of a fractured bone along a path that is not parallel to the intramedullary canal, and once inserted may be radially expanded to fill the intramedullary canal and provide rigid support to the bone during healing. To allow for insertion of the device over a guidewire, and to allow space for an expansion apparatus, the fixation device **1010** may be cannulated along its entire length.

The central portion **1014** may be composite, where composite is defined as at least two non-identical materials deliberately combined to form heterogeneous structures with desired or intended properties. For example, a composite central portion may comprise a metal support structure which is embedded in thermo-chemically activated matrix material. In the present embodiment, the two non-identical materials are the metal which comprises the support structure, and the matrix material. The nose portion **1012** and the attachment portion **1016** may each be non-composite, in that each may comprise one material, such as matrix material, metal or metal alloy, ceramic, or polymer, among others.

The nose portion **1012** of the fixation device **1010** has a distal tip **1018**, and a proximal transition end **1020** where the nose portion **1012** joins the central portion **1014**. The nose portion **1012** may be substantially tapered from the transition end **1020** to the tip **1018**. This taper allows for easier introduction of the nose portion **1012** into the intramedullary canal, and may match the morphology of the distal end of the

intramedullary canal. The nose portion **1012** may be made of a thermo-mechanically or thermo-chemically activated thermoplastic matrix material, and may be radially expandable. The thermo-chemically activated thermoplastic matrix material is configured to be substantially deformable at a first thermo-chemical state, and substantially hardened at a second thermo-chemical state.

The thermoplastic matrix material may comprise a combination of PCLM-12, SMC-7, and A-6. PCLM-12 is a polyaxial copolymer made of about 98/2 (molar) ϵ-caprolactone/glycolide. The polymer is made using stannous octanoate and triethanolamine as the catalyst and initiator, respectively. The composition of PCLM-12 protected in part by U.S. Pat. No. 7,048,753, which is incorporated herein by reference. SMC-7 is a segmented copolymer made of about 88/12 (molar) l-lactide/trimethylene carbonate using 1,3-propanediol and stannous octanoate as the initiator and catalyst, respectively. The composition of SMC-7 is protected by U.S. Pat. Nos. 7,192,437 and 6,342,065, and European Patent 1,057,844, which are incorporated herein by reference. A-6 is a microparticulate nucleating agent, and is protected in part by a number of patents including U.S. Pat. No. 6,413,539 and European Patents 0,737,703 and 0,952,171, which are incorporated herein by reference.

Specifically, the nose portion **1012** may be formed of a matrix material comprising 95 to 99.9% by weight of a blend of PCLM-12 and SMC-7, and 0.1 to 5% of A-6. More specifically, the nose portion may comprise a matrix material comprising a blend of PCLM-12, SMC-7, and A-6, in which the PCLM-12 may range from 30 to 70% by weight, the SMC-7 may range from 30 to 70% by weight, and the A-6 may range from 0.1 to 5% by weight. Still more specifically, the nose portion **1012** may be made of a matrix material comprising 98% by weight of a blend of 45% by weight of PCLM-12 and 55% by weight of SMC-7; and 2% by weight of A-6.

Referring to FIG. **27**, a longitudinal cross-sectional view of a proximal portion of the fixation device **1010** is shown, with detail of the attachment portion **1016** and the central portion **1014**. The attachment portion **1016** is a substantially rigid, slightly curved tube which extends proximally from a proximal end of the central portion **1014**. The attachment portion **1016** may be curved so that it may reach from the substantially straight intramedullary canal to an opening created in the bone, which opening may be transverse to the longitudinal axis of the intramedullary canal. The attachment portion **1016** joins the central portion **1014** at a distal transition end **1030**. At a proximal end **1032** is an opening **1034**. The opening **1034** may be shaped to mate with a handle used the device insertion process.

Slightly recessed from the opening **1034** may be an attachment connection feature **1036**, which may comprise threads, slots, protrusions, grooves or other elements which may be used to connect the device **1010** to hoses, expansion apparatuses, or other devices. The attachment portion **1016** may be made from a rigid material such as a metal or metal alloy, to provide rigid support during manipulation such as insertion or removal of the device **1010**. More specifically, the attachment portion **1016** may be made from cobalt-chrome-molybdenum (CCM).

Between the nose portion **1012** and the attachment portion **1016** extends the central portion **1014**. The central portion **1014** may be generally straight and tube-like, and may be capable of radial expansion, so that in an expanded state within the intramedullary canal it may provide support to the surrounding fractured bone. As set forth previously, the central portion **1014** may be composite, comprising a support structure and a thermo-chemically activated thermoplastic matrix. In the embodiment depicted in FIG. **27**, the support structure **1040** is a laser-cut stent, cut from CCM. At the proximal end of the central portion **1014**, the CCM of the support structure may be continuous with the CCM of the attachment portion **1016**. In alternative embodiments, the CCM of the support structure may be press-fit or otherwise joined to the CCM of the attachment portion.

The support structure **1040** is laser-cut to a pattern of ribs **1042** interconnected by web-like struts **1044**. The laser-cut pattern allows the central portion **1014** to flex when necessary, such as during insertion and removal of the device **1010**. It also allows for radial expansion of the central portion **1014**; when outward pressure is applied from within the central portion, the orientation of the struts shifts to allow expansion. The wavy portions of the struts **1044** can bend and flex, without breaking. One aspect of the laser-cut pattern is that it may minimize elastic recovery such that once expanded, the support structure **1040** may exhibit minimal drift back to its original shape. In other embodiments of the invention, support structures comprising other laser-cut patterns or other methods of manufacture may be included.

During manufacture, the support structure **1040** is embedded in a thermo-mechanically or thermo-chemically activated thermoplastic matrix **1048** through an injection molding process. In FIG. **27**, only the boundaries of the semi-translucent matrix **1048** are shown, so that the support structure **1040** is visible. However, the matrix **1048** is injection molded so that it surrounds the support structure **1040** and the support structure is embedded within it. As set forth previously, the fixation device **1010** is cannulated, so the matrix **1048** is not solid across the transverse cross section of the device; instead the matrix **1048** is a hollow tube in which the support structure is embedded. The inner surface of the tube is an inner bore wall **1050**, while the outer surface is an outer wall **1052**. The matrix **1048** may extend proximally past the proximal end of the central portion **1014** and may surround some fraction of the attachment portion **1016**. At the distal end of the central portion, the matrix **1048** may be continuous with the matrix material comprising the nose portion **1012**, may abut it, or may overlap some of the nose portion.

The matrix **1048** may be made of the same thermo-chemically activated thermoplastic matrix material of which the nose portion **1012** is made. The matrix **1048** may comprise a combination of PCLM-12, SMC-7, and A-6. Specifically, the matrix **1048** may be made of a matrix material comprising 95 to 99.9% by weight of a blend of PCLM-12 and SMC-7, and 0.1 to 5% of A-6. More specifically, the matrix **1048** may comprise a matrix material comprising a blend of PCLM-12, SMC-7, and A-6, in which the PCLM-12 may range from 30 to 70% by weight, the SMC-7 may range from 30 to 70% by weight, and the A-6 may range from 0.1 to 5% by weight. Still more specifically, the matrix **1048** may be made of a matrix material comprising 98% by weight of a blend of 45% by weight of PCLM-12 and 55% by weight of SMC-7; and 2% by weight of A-6.

FIG. **28**A depicts a handle **1100** which may be releasably connected to the proximal end of the fixation device **1010**. The handle **1100** has a handle body **1110**, with a proximal end **1102** and a distal end **1104**. An ergonomic gripping portion **1112** encompasses the body **1110** near its proximal end **1102**. A proximal connection feature **1106** is located at the body proximal end **1102**, and a distal connection feature **1108** is located at the body distal end **1104**. The distal connection feature **1108** is configured to connect with the attachment connection feature **1036** on the fixation device **1010**. In this

embodiment of the invention the distal connection feature **1108** comprises threads, however in other embodiments it may comprise slots, grooves, protrusions, or other elements configured to mate with the attachment connection feature **1036**. Additionally, the distal end **1104** may have a mating feature **1116** configured to mate with the opening **1034** of the attachment portion **1016** of the fixation device **1010**.

FIG. **28**B is an end view of the body proximal end **1102** of the handle **1100**. The proximal connection feature **1106** is seen as a series of threads; however it may comprise threads, slots, grooves, protrusions or other elements, in other embodiments of the invention. Extending lengthwise through the handle is a bore **1114**. When the handle **1100** is connected to the fixation device **1010**, the bore **1114** of the handle **1100** abuts the bore **1017** of the fixation device **1010**, so there is a continuous uninterrupted passageway through the handle **1100** and the fixation device **1010**. The handle may be connected to the fixation device **1010** and used to insert the fixation device **1010** into the intramedullary canal of the bone. The handle may also be used as an intermediate connection piece between an expansion apparatus and a pump system which supplies fluid to the expansion apparatus.

FIGS. **29**-**32** illustrate how the fixation device **1010** may be inserted into the intramedullary canal of a bone. FIG. **29** is a perspective, partially cutaway view of a fractured tibia **2**. To prepare for insertion of the intramedullary device, an opening **4** is drilled in the tibia, distal of the growth plate, so that bone growth will not be disturbed, which may be of special importance in pediatric patients. The intramedullary canal **6** extends substantially the length of the bone, and is surrounded by a wall **8**.

Referring to FIG. **30**, a removable guidewire **1150** may be inserted through the opening **4** into the intramedullary canal **6**, in the direction indicated by direction arrow **1152**. The guidewire may comprise Nitinol or another material which is sufficiently flexible to bend as it passes through the opening **4**.

As seen in FIG. **31**, the fixation device **1010** is connected to the handle **1100** at the proximal end of the attachment portion **1016**. The handle **1100** is used to guide the fixation device **1010** over the guidewire **1150** into the intramedullary canal **6**, along direction **1152**. As set forth previously, fixation device **1010** is cannulated along its entire length, and the handle **1100** has a bore extending its entire length, so both the fixation device and the handle may be guided over the guidewire. The central portion **1014** of the fixation device comprises the flexible support structure **1040** and the thermoplastic matrix **1048**, which make the central portion **1014** sufficiently bendable to enter the intramedullary canal through the opening **4**. Prior to insertion of the fixation device **1010**, the fixation device may be heated in a water bath or by other means so that the thermo-chemically activated thermoplastic matrix **1048** attains the first thermo-chemical state, and is substantially deformable to bend as it enters the opening **4** and straighten as it continues along the guidewire **1150**.

Referring to FIG. **32**, the fixation device **1010** is inserted into the intramedullary canal **6** so that the attachment portion **1016** is just inside the opening **4**. The handle **1100** may be removed, or may remain attached to the device **1010** in preparation for a device expansion procedure. The guidewire **1150** may be removed by pulling it proximally along direction **1154**, out of the intramedullary canal, the device **1010** and the handle **1100**.

Alternatively, the device **1010** may be inserted into the intramedullary canal without the use of a guidewire. The device **1010** is heated to raise the thermoplastic matrix material **1048** to the first thermo-chemical state, attached to the handle **1100**, and inserted into the canal. An expansion apparatus such as that described below may be present in the device **1010** prior to insertion, or it may be inserted into the central bore **1114** after the device **1010** is in the intramedullary canal.

Referring to FIG. **33**, an embodiment of a balloon expansion apparatus is shown. The expansion apparatus **1200** comprises a catheter-like inner tube **1210** (not visible in FIG. **33**), a balloon **1230**, the handle **1110**, and a connection assembly **1250**. The inner tube **1210** and balloon **1230** are configured to be assembled together co-axially, that is, the inner tube **1210** fits concentrically within the balloon **1230**.

Referring to FIG. **34**, the inner tube **1210** is shown. The inner tube **1210** is straw-like in configuration, with a tube body **1212** having a proximal end **1214** and a distal end **1216**. The tube body **1212** may be constructed of a rigid material so that the length of the tube is fixed; it cannot lengthen or shorten along its longitudinal axis. Yet the tube body **1212** may simultaneously be bendable such that it can flex and bend along its transverse axis. Specifically, the tube body **1212** may be constructed of a linearly rigid, yet bendable material such as Nitinol. The flexibility allows the tube **1210** to be compliant enough to be inserted into the intramedullary canal. The linear rigidity prevents the tube **1210** from expanding longitudinally.

A bullet-shaped cap **1218** is at the distal end of the tube body **1212**. Just proximal to the cap **1218**, a series of ports **1220** perforate the tube body **1212**. The ports **1220** are openings from the inside of the tube body **1212** to the outside, and may allow fluid to flow into, or out of, the inner tube.

Referring to FIG. **35**, the balloon **1230** and the connection assembly **1250** are shown. The balloon **1230** is configured to fit over and encompass the inner tube **1210** (not visible), so that only the cap **1218** protrudes from the distal end of the balloon **1230**. A ring-like distal fitting **1232** joins the inner tube **1210** to the balloon **1230** at their distal ends. The distal fitting **1232** tightly joins the tube and the balloon so that they may be manipulated as one during insertion and removal procedures. Additionally, because the more compliant balloon **1230** is joined to the linearly rigid inner tube **1210** at the distal fitting **1232**, the balloon **1230** is prevented from expanding linearly when pressurized fluid is introduced into the tube and the balloon. The balloon **1230** may comprise an elastomeric polymer, such as polyurethane, latex, silicone, or another elastomeric polymer. Alternatively, the balloon **1230** may comprise a non-elastomeric polymer such as PET, UHWPE, or another non-elastomeric polymer.

Referring to FIG. **36**, a cross-sectional view of the proximal ends of the tube **1210**, the balloon **1230**, and the connection assembly **1250**, is shown. A threaded ring **1270** connects the connection assembly **1250** to the proximal connection feature **1106** of the handle **1100**. A connection housing **1256** encompasses the connections and may allow for convenient assembly of the connections. At their proximal ends, the inner tube **1210** protrudes for a short distance out of the balloon **1230**. The proximal end of the inner tube **1210** opens into a first connector recess **1258**, which is indented into the connection housing **1256**. At a right angle to the inner tube **1210**, an inflow fluid connector **1252** also opens into the first recess **1258**. A first flow indicator arrow **1260** indicates how fluid may flow from the inflow fluid connector **1252** into the inner tube **1210**. The proximal end of the balloon **1230** opens into a second connector recess **1262**, which is indented into the connection housing **1256**. At a right angle to the balloon **1230**, an outflow fluid connector **1254** also opens into the second recess **1262**. A second flow indicator arrow **1264** indicates how fluid may flow from the balloon **1230** into the outflow fluid connector **1254**.

Referring to FIG. **37**, the expansion apparatus **1200** is shown inserted into the fixation device **1010** in the intramedullary canal. The balloon **1230** and inner tube **1210** are not visible because they are surrounded by the fixation device **1010**.

Insertion of the expansion apparatus may happen by a variety of methods. In a first method, after the fixation device **1010** is inserted into the intramedullary canal, the handle **1100** remains attached to the fixation device **1010**, and the balloon **1230** and inner tube **1210** (connected at their proximal ends by the connection assembly **1250**) are inserted through the handle and the fixation device. After they are fully inserted, the connection assembly **1250** is connected to the handle **1100** via the threaded ring **1270**. Alternately, in a second method, the handle is detached from the fixation device. The balloon **1230** and the inner tube **1210** are inserted through the handle and attached via the threaded ring to the connection assembly **1250** and the handle **1100**. Then, using the handle to control and guide, the balloon **1230** and the inner tube **1210** are inserted through the opening **4** and into the fixation device **1010**.

Another method for implementing the expansion apparatus includes inserting the apparatus **1200** into the fixation device **1010** prior to inserting the fixation device **1010** into the intramedullary canal. The expansion apparatus **1200** is inserted into the fixation device **1010** and connection assembly **1250** is connected. Once the balloon assembly **1200** is inserted in the fixation device **1010**, fluid hoses are connected to the connection assembly **1250**. An input hose **1302** is connected to the input fluid connector **1252**, and an output hose **1304** is connected to the output fluid connector **1254**. Fluid is introduced into the expansion apparatus, and heated to in turn heat the fixation device **1010** until the thermoplastic matrix material **1048** attains the first thermo-chemical state. Temperature regulation continues as the device **1010** is inserted into the intramedullary canal, so that it remains warm enough to be substantially deformable and flexible to insert. Once the device **1010** is in the intramedullary canal, pressure may be increased within the device to cause radial expansion of the device. In an alternate embodiment of the invention, air instead of fluid may be heated and circulated through the expansion apparatus to warm the surrounding thermoplastic matrix.

Referring to FIG. **38**, the fixation device **1010** and balloon assembly **1200** (not visible in the figure; within the fixation device) are shown connected via the fluid hoses **1302**, **1304** to a cartridge **1350**, which in turn is connected to a pump **1400**. Sterile saline solution, or another sterile, biocompatible fluid is provided to the pump via a bag or other container (not shown) connected to the pump **1400**. The pump **1400** pumps the fluid to the cartridge **1350**, which is capable to regulate the temperature and pressure of the fluid as it flows to and from the balloon assembly **1200**. The cartridge **1350** may comprise heating and cooling sources capable to heat and/or cool the fluid before it enters the balloon assembly **1200**. In an alternative embodiment, the hoses **1302**, **1304** may be connected directly to the pump without the use of the cartridge **1350**.

Following connection of the cartridge **1350** to the pump **1400** and the balloon assembly **1200**, the balloon assembly may be expanded, to result in the radial expansion of the fixation device **1010** within the intramedullary canal. Fluid can flow through the balloon assembly in a continuous flow, flowing in through the input hose **1302** into the inner tube **1210**, out the ports **1220** into the balloon **1230**, and out of the balloon through the output hose **1304**.

Fluid is supplied by the pump **1400** to the cartridge **1350** and pumped through the input hose **1302** into the inner tube **1210**. At the distal end of the inner tube **1210**, the fluid can move out of the tube **1210** through the ports **1220**, and into the balloon **1230**. As more fluid is added, the length of the balloon **1230** is filled and the balloon expands radially, contacting the inner bore wall **1050** of the matrix **1048** of the fixation device **1010**. The heated fluid within the balloon **1230** heats the matrix **1048**, transforming it from the substantially hardened second thermo-chemical state to the substantially deformable first thermo-chemical state. Pressure is maintained on the fluid in the balloon **1230**, and the deformable heated matrix **1048** is expanded radially in response to the expansion of the balloon **1230**. The outer wall **1052** of the matrix contacts the wall **8** of the intramedullary canal. The deformable heated matrix **1048** can conform to the specific morphology of the wall **8**, filling in any irregularities in the wall. As the heated matrix **1048** expands, the embedded support structure **1040** also expands radially, allowed to by the configuration of the rods **1042** and the flexible struts **1044**. The nose portion **1012** of the fixation device **1010** may also radially expand. The expanded diameters of the non-composite nose portion **1012** and the composite central portion **1014** may be the same, or alternatively, the central portion **1014** may expand to a greater expanded diameter than the nose portion **1012**.

Once the device **1010** is sufficiently radially expanded to provide support to the fractured bone, pressure is maintained and cooled fluid may be pumped through the balloon assembly. Fluid is cooled by the cartridge **1350** and pumped in through the input hose **1302**. As the cooled fluid passes through the balloon **1230**, the surrounding matrix **1048** is cooled, and attains the substantially hardened second thermo-chemical state. The hardened matrix **1048** holds the embedded support structure **1040** in its now expanded configuration, and together they provide support to the surrounding fractured bone. Once the matrix **1048** is sufficiently cooled and hardened, pressure is lowered and the fluid may be pumped out of the balloon and inner tube, and the balloon assembly withdrawn from the fixation device **1010**. The handle **1100** is detached from the attachment end **1016** of the fixation device, leaving the now expanded fixation device **1010** in the intramedullary canal, as shown in FIG. **39**. The opening **4** in the bone may be covered with a removable plug, and the tissues closed.

Positioning of the fixation device **1010** may be revisable if necessary. To revise or remove, the opening **4** may be re-opened, and a balloon expansion apparatus **1200** is attached to the handle **1100** and introduced into the bore **1114** of the fixation device **1010**, and connected at the attachment connection feature **1036**. The cartridge **1350** and pump **1400** are connected to the expansion apparatus **1200** via the connection assembly **1250**, and heated fluid is introduced into the balloon **1230**. Pressure is increased to inflate the balloon **1230**, and the heated fluid warms the thermo-plastic matrix material **1048** until it is at the pliable first thermo-chemical state. The position of the fixation device **1010** may be revised by gripping the handle **1100** and moving the device **1010**. Once the desired position is found, cool fluid is pumped through the device to cool the thermo-plastic matrix **1048** to the hardened second thermo-chemical state. The fluid pressure is lowered and the expansion apparatus is removed.

Alternately, removal instead of repositioning of the device **1010** may occur after warming the device to the first thermo-chemical state. The fluid pressure is lowered to contract the expansion apparatus **1200**, and the device is pulled out through the opening **4**. The warmed thermoplastic matrix material **1048** will be sufficiently deformable to allow the device **1010** to contract sufficiently as it passes out the opening **4**.

FIGS. **40** through **43** illustrate alternative methods of heating the fixation device **1010** to raise the temperature of the thermoplastic matrix material **1048** to the substantially deformable first thermo-dynamic state. FIG. **40** depicts the fixation device **1010** with an external heat source **1360** connected by a lead **1362** to the attachment portion **1016** and the support structure **1040**. Energy is conducted from the heat source **1360** to the support structure **1040**, which increases in temperature and warms the surrounding thermoplastic matrix material **1048**. An expansion apparatus such as expansion apparatus **1200** may be inserted into the fixation device **1010**, connected to a pump such as pump **1400** and used to apply fluid or air pressure to expand the heated device.

FIG. **41** depicts a flexible, expandable heating system **2250** used in conjunction with a balloon expansion apparatus **2200** which is similar in structure to balloon expansion apparatus **1200**. In FIG. **41**, the balloon **2230** is shown as partially expanded so that details of the heating system may be seen. The expandable heating system **2250** may comprise a heat source **2252** and flexible conductive elements **2254** disposed on the external surface of the balloon **2230**. Alternately, the flexible conductive elements may be integrated into the composition of the balloon. The conductive elements **2254** may comprise copper or another suitably conductive material. As the balloon is filled with fluid or air, heat is introduced from the heat source **2252** through the conductive elements **2254**, heating the fluid or air within the balloon. The conductive elements **2254** are configured to flex and separate, without breaking, as the balloon expands. As the balloon expands within the fixation device **1010**, heat from the fluid or air is transferred to the surrounding thermoplastic matrix material **1048**. Heat may also transfer directly from the expandable heating system **2250** to the surrounding matrix material. Once the fixation device is sufficiently expanded, heat is turned off to the heating system **2250**. Pressure is maintained in the balloon until the thermoplastic matrix cools to the hardened second thermo-chemical state. Then the air or fluid is removed, and the balloon expansion apparatus may be removed.

FIG. **42** depicts a heating system **2350** which is similar in operation to heating system **2250**, except that it comprises a heat source **2352** and flexible heating elements **2354** disposed on an expandable sleeve **2356** which is separate from the balloon. Alternately, the flexible conductive elements may be integrated into the composition of the sleeve. The expandable sleeve **2356** is sized to fit over a balloon such as balloon **1230** of balloon expansion apparatus **1200** or a similar balloon. The expandable sleeve **2356** may be placed over the balloon **1230**, and the sleeve and balloon inserted together into an intramedullary fixation device such as device **1010**. As the balloon is filled with fluid or air, heat is introduced from the heat source **2352** through the flexible heating elements **2354**, warming the fluid or air within the balloon. The heating elements **2354** are configured to flex and separate, without breaking, as the balloon expands. As the balloon expands within the fixation device **1010**, heat from the fluid or air is transferred to the surrounding thermoplastic matrix material **1048**. Heat may also transfer directly from the expandable heating system **2350** to the surrounding matrix material. Once the fixation device is sufficiently expanded, heat is turned off to the heating system **2350**. Pressure is maintained in the balloon until the thermoplastic matrix cools to the hardened second thermo-chemical state. Then the air or fluid is removed, and the balloon expansion apparatus may be removed.

Alternatively, a rigid, or non-flexible sleeve with integrated heating elements (not shown) could be used in a manner similar to the expandable sleeve **2356**. A non-flexible sleeve may be placed over a balloon expansion apparatus and inserted into an intramedullary fixation device such as those previously described. Heat is introduced through the heating elements, warming the surrounding thermoplastic matrix material. Once the material is sufficiently warmed to attain the first thermo-chemical state and becomes pliable, the non-flexible sleeve is removed, leaving the balloon expansion apparatus in the fixation device. The balloon expansion apparatus may then be expanded with pressurized fluid or air to expand the surrounding intramedullary fixation device.

Referring to FIG. **43**, an air heating and pressure control system **2400** is shown connected to the balloon expansion apparatus **1200** (not visible; inside the fixation device **1010**) and fixation device **1010**. Air heating and pressure control system **2400** comprises a pump **2402** which supplies and regulates pressure to the system, a heat source **2404** which supplies heat to the system, input hose **2406** which carries air into the expansion apparatus, and output hose **2408** which carries air out of the expansion apparatus. Air heating and pressure control system **2400** may work similarly to the cartridge **1350** and pump **1400** described previously, except that in this system air is heated and circulated throughout the balloon expansion apparatus instead of fluid.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. It is appreciated that various features of the above-described examples can be mixed and matched to form a variety of other alternatives. For example, support structure and matrix materials and configuration features can vary, as can the method used to expand the device. As such, the described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A method for inserting a bone stabilization device into the intramedullary canal of a bone, the bone stabilization device including an elongated body configured for insertion into the intramedullary canal of a bone, the body having a first end, a second end, and a longitudinal axis extending between the first and second ends, the body including a polymer with a deformation temperature greater than 37 degrees Celsius, wherein the polymer is relatively deformable at a temperature above the deformation temperature and relatively rigid at a temperature below the deformation temperature, the device, while the polymer is at a temperature above the deformation temperature, being responsive to a bending force to bend during insertion into the intramedullary canal of the bone, and the device, while the polymer is at a temperature below the deformation temperature, being relatively rigid and able to provide reinforcement to the bone sufficient to promote healing of the fractured bone, the method comprising:

raising the temperature of the polymer above the deformation temperature so that the polymer is relatively deformable;

after raising the temperature of the polymer above the deformation temperature, inserting the bone stabilization device into the intramedullary canal of the bone; and

after inserting the bone stabilization device into the intramedullary canal of the bone, lowering the temperature of the polymer below the deformation temperature so that the polymer is relatively rigid and able to provide reinforcement to the bone.

2. The method of claim 1 wherein lowering the temperature of the polymer comprises allowing time for the polymer to dissipate heat to the surrounding bone.

3. The method of claim 1 wherein lowering the temperature of the polymer comprises actively cooling the polymer by removing heat from the polymer via a heat removal apparatus.

4. The method of claim 1 wherein inserting the bone stabilization device into the intramedullary canal of the bone comprises inserting the device through a delivery tube.

5. The method of claim 1 wherein inserting the bone stabilization device into the intramedullary canal of the bone comprises inserting the device over a guidewire.

6. The method of claim 1 wherein inserting the bone stabilization device includes deforming the bone stabilization device while it is above the deformation temperature so that it conforms to a non-linear insertion path into the bone.

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